Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Device Information							
Device Identifier (DI) Information							
Issuing Agency	Organization accredited by FDA to operate a system for the issuance of UDIs.	Choose a value from the drop down LOV.	None	Required	NA	GS1; HIBCC; ICCBBA	YES
Primary DI Number	An identifier that is the main (primary) lookup for a medical device and meets the requirements to uniquely identify a device through its distribution and use. The primary DI number will be located on the base package, which is the lowest package level of a medical device containing a full UDI. For medical devices without packaging, the primary DI number and full UDI may be on the device itself.	Enter the Device Identifier (DI) Number. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	None	Required	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	YES
Device Count	Number of medical devices in the base package.	Enter the number of devices. Example: Base Package = Box of 100 gloves; Primary DI = 101; Device Count = 100.	None	Required	Type: Num. Length: 7	NA	YES

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Unit of Use DI Number	An identifier assigned to an individual medical device when a UDI is not labeled on the individual device at the level of its unit of use. Its purpose is to associate the use of a device to/on a patient.	Enter the Unit of Use DI Number. Must be from same Issuing Agency as Primary DI. Unit of Use DI is an identifier used by hospital staff and Materials Management to account for a single device when the UDI is labeled on a higher level of packaging. The Unit of Use DI does not appear on the label. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters If Device Count = 1, cannot add Unit of Use DI Number.	Edit	Conditionally Required* *If Device Count >1.	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Labeler DUNS Number^	Business number issued by Dun & Bradstreet (D&B) that is used to associate the Labeler (Company) name and address to a given version of model of a device in GUDID.	Choose appropriate DUNS Number from drop down LOV. To ensure data consistency for the GUDID, DUNS number submitted to the GUDID should associate to the company name that appears on the device label; ideally the address associated with the DUNS number should also match the address on the device label, but since address is not displayed to the GUDID public user, this is not a requirement for data consistency. All edits to information connected to the Labeler DUNS Number must be done through Dun & Bradstreet. No edits of DUNS information will be permitted in the GUDID.	Edit* *Other Labeler DUNS listed to your GUDID account can be selected. No edits of DUNS info will be permitted.	Required	NA	Labeler DUNS LOV	no
Company Name	Company name associated with the labeler DUNS Number entered in the DI Record.	Auto populated based on the Labeler DUNS Number The labeler company name submitted to the GUDID should match the company name on the device label.	NA	Auto Populated	NA	NA	no

^ - GUDID data elements that are not released to the public.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Company Physical Address^	Company physical address associated with the labeler DUNS Number entered in the DI Record.	Auto populated based on the Labeler DUNS Number Ideally, this address should match the labeler address as shown on the device label but since this data element is not be displayed to the GUDID public user, this is not a requirement for data consistency.	NA	Auto Populated	NA	NA	no
Brand Name	The Proprietary/Trade/Brand name of the medical device as used in device labeling or in the catalog. This information may 1) be on a label attached to a durable device, 2) be on a package of a disposable device, or 3) appear in labeling materials of an implantable device. The brand name is the name that is typically registered with USPTO and have the ® and/or ™ symbol.	Enter the Brand Name. Only symbols, ® and ™ will be supported for the current production release of GUDID. NOTE: per Edit Rules, you will not be able to change ® or ™ (if entered) after the Grace Period. Enter NA if the device does not have a Brand Name.	None	Required	Type: Alphanum. Length: 80	NA	YES

^ - GUDID data elements that are not released to the public.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Version or Model	The version or model found on the device label or accompanying packaging used to identify a category or design of a device. The version or model identifies all devices that have specifications, performance, size, and composition within limits set by the labeler.	Enter the Version or Model. Version/Model can be any distinguishing string of letters and/or numbers. Catalog Number can be entered if device does not currently have a Version or Model. If the device does not have a version, model or catalog number, enter a concept that can be used to identify all devices that have specifications, performance, size, and composition within limits set by the labeler.	None	Required	Type: Alphanum. Length: 80	NA	YES
Catalog Number	The catalog, reference, or product number found on the device label or accompanying packaging to identify a particular product.	Enter the Catalog or Reference Number. Catalog/Reference number can also serve as Version/Model if it represents the devices that have specifications, performance, size, and composition within limits set by the labeler.	Add Delete Edit	Optional	Type: Alphanum. Length: 80	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Device Description	Additional relevant information about the device that is not already captured as a distinct GUDID data attribute.	Enter device description. Device description should include any description found on the device label to support user comparison of the device label to the GUDID device record. Otherwise, include any additional description or text found in the device labeling.	Add Delete Edit	Optional	Type: Alphanum. Length: 2000	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Commercial Distribution							
DI Record Publish Date	Indicates the date the DI Record is published and available via Public Search.	Choose date from calendar or manually enter date in new format (yyyy-mm-dd). This date determines the Grace Period, presently set to 30 calendar days. Grace Period starts the day after the DI Record Publish Date. We recommend you set this date to be a future date to allow time to ensure accurate data entry.	None	Required	Type: Date Format (yyyy-mm-dd) Length: 10	NA	no
Commercial Distribution End Date	Indicates the date the device is no longer offered for commercial distribution by the labeler on record. See 21 CFR 807.3(b) for exceptions. The device may or may not still be available for purchase in the marketplace.	Choose date from calendar or manually enter date in new format (yyyy-mm-dd).	Add Delete Edit	Optional	Type: Date Format (yyyy-mm-dd) Length: 10	NA	no
Commercial Distribution Status	Indicates whether the device is in commercial distribution as defined under 21 CFR 807.3(b).	Auto populated based on Commercial Distribution End Date. If no Commercial Distribution End Date is entered, the status is 'In Commercial Distribution'	NA	Auto Populated	NA	In Commercial Distribution; Not in Commercial Distribution	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Alternative or Additional Identifiers							
Direct Marking (DM)		Direct Marking (DM) data elements only apply to devices subject to 21 CFR 801.45.					
Device Subject to Direct Marking (DM), but Exempt	The device is exempt from Direct Marking requirements under 21 CFR 801.45.	Select checkbox if appropriate. Labeler should select the checkbox "Device Subject to Direct Marking (DM), but Exempt" only if the device: (1) is intended to be used more than once and (2) is intended to be reprocessed before each use, but also (3) meets any one of the exception criteria outlined under 21 CFR 801.45(d). If the device is not required to be directly marked under 21 CFR 801.45(a), then this box should not be checked.	Add Delete Edit	Conditionally Required* *If device is subject to 801.45	Type: Boolean	NA	no
DM DI Different from Primary DI	Indicates that the DM DI Number is different than the Primary DI Number.	Select checkbox if appropriate.	Add Delete Edit	Conditionally Required* *If device is subject to 801.45	Type: Boolean	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
DM DI Number	An identifier that is marked directly on the medical device and is different than the Primary DI Number; only applicable to devices subject to Direct Marking requirements under 21 CFR 801.45.	Enter Direct Marking DI Number. Must be from same Issuing Agency as Primary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters	Add Delete Edit	Conditionally Required* *If device subject to 801.45 and 'DM DI Different from Primary DI' is checked	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	no

^ - GUDID data elements that are not released to the public.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Secondary DI							
Issuing Agency	Name of Secondary DI Issuing agency.	Choose a value from the drop down LOV.	None	Optional	NA	GS1; HIBCC; ICCBBA; NDC/NHRIC	no
Secondary DI Number	An identifier that is an alternate (secondary) lookup for a medical device that is issued from a different issuing agency than the primary DI. Under 21 CFR 830.40(a), only one device identifier from any particular system for the issuance of UDIs may be used to identify a particular version or model of a device.	Enter Secondary DI Number. If your product is labeled with a UDI from more than one issuing agency (for regulatory or marketing reasons), you must choose one issuing agency system as the Primary DI and enter the other issuing agency information here, as a Secondary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters NDC: Numeric (Num.), with 10 or 11 digits, may include 2 hyphens	None	Optional	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Package DI	Every device package shall bear a UDI, 21 CFR 801.20(a)(2). Package DIs do not need their own DI record; instead package information should be entered in the Package DI section of the Primary DI record for that device. According to 21 CFR 801.3, a package is defined as a fixed quantity of a particular version or model of a device.						
Package DI Number	A device identifier for the package configuration that contains multiple units of the base package (does not include shipping containers).	Enter Package DI Number. Must be from same Issuing Agency as Primary DI. Data type and field length are determined by the individual Issuing Agency structure. GS1: Numeric (Num.), with 14 digits HIBCC: Alphanumeric (Alphanum.), with 6-23 characters ICCBBA: Alphanumeric, with 10 or 16 characters Examples: Box of Gloves = DI 101 4 Boxes of Gloves (DI 101) in a Carton = Package DI 201 (the UDI on the Carton) 5 Cartons (Pkg DI 201) in a Case = Package DI 301 (the UDI on the Case) 10 Boxes of Gloves (DI 101) in a Carton = Package DI 202 (the UDI on the Carton).	Add	Conditionally Required* *If device is available in higher levels of packaging	Type: Num. or Alphanum. Length: min-6, max-23* *defined by Issuing Agency structure.	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Quantity per Package	The number of packages with the same Primary DI or Package DI within a given packaging configuration.	Enter the number of devices per package. The quantity of a package configuration must be >1. Examples: Package – Carton, Pkg DI 201 contains 4 boxes of DI 101; the quantity per package is 4. Package – Case, Pkg DI 301 contains 5 cartons of Pkg DI 201; the quantity per package is 5. Package – Carton, Pkg DI 202 contains 10 boxes of DI 101; the quantity per package is 10.	Add	Conditionally Required* *If Package DI is entered	Type: Num. Length: 9	NA	no
Contains DI Package	The Primary DI for the base package or the Package DI for any lower level package configuration contained within a given package configuration.	Choose a value from the drop down LOV. Examples: Package DI 201 (Carton) contains base package DI 101. Package DI 202 (Carton) contains base package DI 101. Package DI 301 contains lower level Package DI 201 (Carton).	Add	Conditionally Required* *If Package DI is entered	NA	DI numbers; base package and all lower levels of packaging	no
Package Type^	Text to describe the outer packaging of the product and enables users to understand higher level packaging configurations.	Enter name or description of package. This field is free text. There is no implied definition or standard quantity to any package name.	Add	Optional	Type: Alphanum. Length: 20	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Package Discontinue Date	Indicates the date this particular package configuration is discontinued by the labeler.	Choose date from calendar or manually enter in format (yyyy-mm-dd). Discontinuation of a package is directly related to the discontinuation of the primary DI of the base package. However, a package can also be discontinued without the discontinuation of the base package.	Add	Conditionally Required* *If Package DI Number and Commercial Distribution End Date are entered, must also enter Package Discontinue Date	Type: Num. (date format) Length: 10	NA	no
Package Status	Indicates whether the package is in commercial distribution as defined under 21 CFR 807.3(b).	Auto populated based on Package Discontinue Date. If Package DI and related elements are entered and no Package Distribution End Date is entered, the status is 'In Commercial Distribution.'	NA	Auto Populated	NA	In Commercial Distribution; Not in Commercial Distribution	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Customer Contact							
Customer Contact Phone	Phone number for the Customer contact; to be used by patients and consumers for device-related questions.	Enter phone number. For North American numbers, type 10-digit number with or without punctuation. For international numbers, start with "+" and type number without punctuation. This phone number could be the 1-800 number that appears on the device labeling or the company website. Labelers can identify a Customer Contact phone number and Customer Contact email address for each device record. If an email is entered and you don't have a Customer Contact phone number, please enter '9999999999'	Add Delete Edit	Conditionally Required* *ONLY required if Customer Contact Email is entered	Type: Num. Length: 10 (North American numbers); 20 (all others)	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Customer Contact Email	Email for the Customer contact; to be used by patients and consumers for device-related questions.	Enter email address. This email address could be the same one that appears on the device labeling or the company website. Labelers can identify a Customer Contact email and a Customer Contact phone number for each device record. If a phone number is entered and you don't have a Customer Contact email, please enter 'xx@xx.xx'	Add Delete Edit	Conditionally Required* *ONLY required if Customer Contact Phone is entered	Type: Alphanum. Length: 100	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Device Status							
Human Cell, Tissue or Cellular or Tissue-Based Product (HCT/P)	Indicates that the product contains or consists of human cells or tissues that are intended for implantation, transplantation, infusion, or transfer into a human recipient as defined under 21 CFR 1271.3.	Select checkbox if DI record is for a product defined under 21 CFR 1271.3 If checked, the labeler must assign and label each HCT/P device with a distinct identification code, per 21 CFR 1271.290(c). The distinct identification code may take the form of a Donation Identification Number (DIN) , serial number, lot number, or a combination of these production identifiers (PIs). Labelers of HCT/Ps regulated as medical devices should select the appropriate type of PI that appears on the label of the device.	Add Delete Edit	Optional If no data is provided, 'No' is stored	Type: Boolean	NA	no
Kit	Indicates that the device is a convenience, combination, in vitro diagnostic (IVD), or medical procedure kit. Kits are a collection of products, including medical devices, that are packaged together to achieve a common intended use and is being distributed as a medical device.	Select checkbox if DI record is for a kit. Do not check if the device is a constituent part of a kit.	None	Optional If no data is provided, 'No' is stored	Type: Boolean	NA	YES

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Combination Product	Indicates that the product is comprised of two or more regulated products that are physically, chemically, or otherwise combined or mixed and produced as a single entity; packaged together as a single package; or packaged separately for the intended use together as defined under 21 CFR 3.2(e). At least one of the products in the combination product must be a device in this case.	Select checkbox if DI record is for a combination product. Do not check if the device is a constituent part of a combination product.	None	Optional If no data is provided, 'No' is stored	Type: Boolean	NA	YES

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Premarket							
Device Exempt from Premarket Submission	FDA Premarket submission is not required for this device.	Select checkbox if FDA has by regulation exempted this device from premarket submission requirements; or for pre-amendment devices that are not subject to premarket submission requirements. If left unselected, a 'No' is stored and a Premarket Submission Number should be entered below.	None	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.	Type: Boolean	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
FDA Premarket Submission Number^	Number associated with the regulatory decision regarding the applicant's legal right to market a medical device for the following submission types: 510(k), PMA, PDP, HDE, BLA, and NDA.	Enter current FDA Premarket Submission Number(s). Each DI record represents a version or model of a device. For each DI record, you must submit the original premarket authorization number and the supplement number through which you obtained approval or clearance for the version or model identified in the DI record, as required by 830.310(b)(11). FDA Premarket Numbers should be verified with the FDA PMA or 510(k) database to make sure the Number represents the subject of the device record. Device records should be updated with additional numbers in the future, as needed. Example: PMA #123456 should be entered as 'P123456.'	Add	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.	Type: Alphanum. Length: 8	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Supplement Number^	Number assigned by FDA to a supplemental application for approval of a change in a medical device with an approved PMA, HDE, or PDP.	Enter all valid Supplement Numbers. Each DI record represents a version or model of a device. For each DI record, you must submit the original premarket authorization number and the supplement number through which you obtained approval for the version or model identified in that DI record, as required by 830.310(b)(11). Although not all PMA supplements are applicable to a given model or version, if FDA approves a subsequent supplement applicable to that version or model, the GUDID DI record must be updated with that supplement number, in accordance with 21 CFR 830.330(b). 30 day notice supplements should be submitted ONLY if the 30 day notice impacts the device design specifications, or performance of the finished devices. Do not enter alpha characters. Example: Supplement 4 should be entered as 004.	Add	Conditionally Required* *Premarket Submission Number OR exempt status fulfills regulatory requirement.	Type: Num. Length: CDRH - min-1, max-3 CBER - min-1, max-4	NA	no

^ - GUDID data elements that are not released to the public.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
FDA Product Code							
Product Code	Classification for devices issued by the FDA.	Enter all applicable Product Codes, three-letter code. For all PMA and 510k devices, Product Codes are assigned in the FDA approval or clearance letter, respectively. For Class I and exempt devices, the device Product Code may be self-identified.	Add Delete Edit	Conditionally Required* *Unless device is a kit or IVD with a BL premarket submission number	Type: Alpha Length: 3	FDA Product Code list	no
Product Code Name	Name associated with the three-letter Product Code.	Auto populated based on 3-letter Product Code	NA	Auto Populated	NA	NA	no
FDA Listing							
FDA Listing Number^	Number assigned by FDA during Registration and Listing to all devices in commercial distribution, regardless of pre-market authorization requirements per 21 CFR 807.28(f).	Enter all relevant listing numbers that enable the labeler to commercially distribute the given version or model of device. Listing number is optional for HCT/P devices with a BLA premarket number.	Add	Conditionally Required* *Unless device is an HCT/P with a BL premarket submission number	Type: Alphanum. Length: 7	NA	no

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Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
GMDN							
Code^	GMDN Preferred Term (PT) Code is a unique five-digit code used to identify common device types. This PT Code is assigned to medical devices and related health care products for the purposes of grouping and categorization.	Enter all applicable GMDN Preferred Term Codes or FDA PT Codes. Each device record must have at least one assigned GMDN Code/FDA PT Code; DI records are allowed >1 GMDN Code/FDA PT Code, if necessary. Must enter GMDN Code OR FDA PT Code, please don't enter both codes for the same GMDN Name and Definition. For GMDN Codes: Enter only the 5-digit number, omit the 'P' For FDA PT Codes: Enter the 4-letter code. The FDA PT Codes are assigned to each GMDN term, used in place of a GMDN Code. They enable labelers to assign a GMDN term to their GUDID submission until a GMDN Code can be obtained from the GMDN Agency. The FDA PT Codes can be found in the Find FDA PT Code Module on the GUDID website. For more information, see the GUDID Final Guidance. The FDA PT Codes can be found in the Find FDA PT Code Module on the GUDID website.	Add Delete Edit	Required	GMDN -- Type: Num. Length: 5 FDA PT Code: Type: Alpha Length: 4	NA	no
Name	Name of the common device type associated with the GMDN Preferred Term Code/FDA PT Code.	Auto populated based on GMDN Preferred Term Code/FDA PT Code.	NA	Auto Populated	NA	NA	no

^ - GUDID data elements that are not released to the public.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Definition	Definition of the common device type associated with the GMDN Preferred Term Code/FDA PT Code.	Auto populated based on GMDN Preferred Term Code/FDA PT Code.	NA	Auto Populated	NA	NA	no
Device Characteristics							
For Single-Use	Indicates that the device is intended for one use or on a single patient during a single procedure.	Choose Yes/No from the drop down list.	None	Required	Type: Boolean	Yes/No	YES

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Production Identifier(s) in UDI							
Lot or Batch Number	The number assigned to one or more device(s) that consist of a single type, model, class, size, composition, or software version that are manufactured under essentially the same conditions and that are intended to have uniform characteristics and quality within specified limits. This number is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution and use to be determined.	Choose Yes/No from the drop down list. For stand-alone software, select Yes to indicate that the software version number will be represented as a Lot or Batch number	Add Delete Edit	Required	Type: Boolean	Yes/No	no
Manufacturing Date	The date on which a device is manufactured. This date is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution and use to be determined.	Choose Yes/No from the drop down list.	Add Delete Edit	Required	Type: Boolean	Yes/No	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Serial Number	The number that allows for the identification of a device, indicating its position within a series. This number is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution and use to be determined.	Choose Yes/No from the drop down list.	Add Delete Edit	Required	Type: Boolean	Yes/No	no
Expiration Date	The date by which the label of a device states the device must or should be used. This date is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution and use to be determined.	Choose Yes/No from the drop down list.	Add Delete Edit	Required	Type: Boolean	Yes/No	no

^ - GUDID data elements that are not released to the public.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Donation Identification Number	The Donation Identification Number is applicable to devices that are also regulated as HCT/Ps and is a number that is assigned to each donation. This number/code is required to be part of the UDI when included on the label in order to provide the means to track the device back to its manufacturing source or otherwise allow the history of the device manufacturing, packaging, labeling, distribution and use to be determined.	Choose Yes/No from the drop down list. This PI is only applicable to HCT/P products regulated as medical devices.	Add Delete Edit	Required	Type: Boolean	Yes/No	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Latex Information							
Device required to be labeled as containing natural rubber latex or dry natural rubber (21 CFR 801.437).	Indicates that the device or packaging contains natural rubber that contacts humans as described under 21 CFR 801.437. Choosing 'Yes' indicates that the device label or packaging contains one of the following statements: (1) "Caution: This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions", (2) This Product Contains Dry Natural Rubber", (3) Caution: The Packaging of This Product Contains Natural Rubber Latex Which May Cause Allergic Reactions" or (4) "The Packaging of This Product Contains Dry Natural Rubber".	Choose Yes/No from the drop down list.	None	Required	Type: Boolean	Yes/No	YES

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Device labeled as "Not made with natural rubber latex"	Indicates that natural rubber latex was not used as materials in the manufacture of the medical product and container and the device labeling contains this information. Only applicable to devices not subject to the requirements under 21 CFR 801.437. Not all medical products that are NOT made with natural rubber latex will be marked.	Select checkbox if appropriate. Only applicable if the response to "Device required to be labeled as containing natural rubber latex or dry natural rubber" is "No". Optional element for labelers who include a statement of 'latex-free' on their label or in their labeling. FDA finds these statements: 'latex-free' and 'does not contain latex', to be not scientifically supportable and strongly recommends they not be used in medical product labeling. Instead FDA recommends the use of the statement 'Not made with natural rubber latex." It is not assumed that all devices NOT made with natural rubber latex are marked; therefore this is an optional element for the labelers who choose to make a statement in the labeling.	Add Delete Edit	Optional If no data is provided, "No" is stored	Type: Boolean	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Prescription Status							
Prescription Use (Rx)	Indicates that the device requires a prescription to use.	Select checkbox if appropriate. Can select both Rx and OTC for one DI record.	Add Delete Edit	Optional If no data is provided, "No" is stored	Type: Boolean	NA	no
Over the Counter (OTC)	Indicates that the device does not require a prescription to use and can be purchased over the counter (OTC).	Select checkbox if appropriate. Can select both Rx and OTC for one DI record.	Add Delete Edit	Optional If no data is provided, "No" is stored	Type: Boolean	NA	no
MRI Safety Status							
What MRI safety information does the labeling contain?	Indicates the MRI Safety Information, if any, that is present in the device labeling. Please see the ASTM F2503-13 standard for more information.	Choose a value from the drop down LOV. The final rule does not require MRI-compatibility testing; it only requires submission of information regarding MRI-compatibility that the labeler already possesses.	Edit* *ONLY if changing from 'Labeling does not contain…' to other MR status (Safe, Unsafe, Conditional). Otherwise, NO changes are allowed.	Required	NA	MR Safe, MR Unsafe, MR Conditional, Labeling does not contain MRI Safety information	YES

^ - GUDID data elements that are not released to the public.

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Clinically Relevant Size							
Size Type	Dimension type for the clinically relevant measurement of the medical device.	Choose a value from the drop down LOV. If the desired Size Type is not in the current list, select 'Size Text, specify' and the data element 'Size Type Text' will appear (see below). It is expected that the 'Size Text, specify' will only be available for a limited time. Use this option to help us build a list of values that are appropriate for your device type. GUDID reserves the right to review all suggestions before adding values to the Size Type LOV. More than one Size Value per Type and more than one Size Type may be added to each DI record.	Add	Conditionally Required* *If device is available in more than one size	NA	Circumference ; Depth; Device Size Text, specify; Catheter Gauge ; Outer Diameter; Height; Length; Lumen/Inner Diameter; Needle Gauge; Total Volume; Width; Weight; Pressure; Pore Size; Area/Surface Area; Angle	no
Size Value	Numeric value for the clinically relevant size measurement of the medical device.	Enter numeric value for size. Decimals are accepted; fractions are not accepted. Each Size Value should be entered separately. GUDID is not accepting Size Value as a range at this time.	Add	Conditionally Required* *Required if device is available in more than one size	Type: Num. Length: 40	NA	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Size Unit of Measure	The unit of measure associated with each clinically relevant size.	Choose a value from the drop down.	Add	Conditionally Required* *Required if device is available in more than one size	NA	For length: Centimeter; Decimeter; Feet; Femtometer; Inch; Kilometer; Meter; Micrometer; Millimeter; Nanometer; Picometer; Yard; For area: Square centimeter; Square foot; Square inch; Square meter; Square millimeter For weight: Gram; Kilogram; Microgram; Milligram; Metric Ton; Pound; Ton For total volume: Centiliter; Cubic Inch; Cup; Deciliter; Femtoliter; Fluid Ounce; Gallon; Kiloliter; Liter; Microliter; Milliliter; Nanoliter; Picoliter; Pint; Quart For gauge: French; Gauge For angle: Degree For pressure: Pound per Square Inch; millibar; KiloPascal; Hertz; Millibar	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Size Type Text	Additional undefined device size not represented in the GUDID Size Type LOV.	Enter Size Type, Size Unit and Unit of Measure for each entry.	Add	Conditionally Required* *Required if 'Size Text, specify' is selected above	Type: Alphanum. Length: 200	NA	no
Storage and Handling							
Storage and Handling Type	Indicates storage and handling requirements that are required for the device including temperature, humidity, and atmospheric pressure.	Choose a value from the drop down LOV. Conditions of the Storage and Handling Type are measured below as a range, with a Low Value and a High Value. More than one Storage and Handling Type can be added per device record.	Add Delete Edit	Optional	NA	Handling Environment Atmospheric Pressure; Handling Environment Humidity; Handling Environment Temperature; Special Storage Conditions; Storage Environment Atmospheric Pressure; Storage Environment Humidity; Storage Environment	no

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Low Value	Indicates the low value for storage and handling requirements.	Enter a number for Low Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the lower end of that range When Storage and Handling value is less than a value, enter the number here When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling High Value	Add Delete Edit	Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record	Type: Num. Length: 6	NA	no
High Value	Indicates the high value for storage and handling requirements.	Enter a number for High Value. Must enter at least one value, Low or High but can enter both Low Value and High Value, if needed. When Storage and Handling value is a range, this is the higher end of that range When Storage and Handling value is greater than a value, enter the number here When Storage and Handling value is exactly a value, enter the value here and in Storage and Handling Low Value	Add Delete Edit	Conditionally Required* *One value (Low or High) is required if Storage and Handling Type is added to the device record	Type: Num. Length: 6	NA	no

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Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Unit of Measure	The unit of measure associated with the storage and handling conditions.	Choose a value from the drop down LOV.	Add Delete Edit	Conditionally Required* *Required if Storage and Handling Type is added to the device record	NA	Degrees Celsius; Degrees Fahrenheit; Degrees Kelvin; Kilo Pascal; Percent (%) Relative Humidity, Millibar	no
Special Storage Conditions	Indicates any special storage requirements for the device.	Enter any other storage conditions. For devices kept at room temperature, or other standard conditions, input that information here.	Add Delete Edit	Conditionally Required* *Required if 'Special Storage Conditions' is selected above	Type: Alphanum. Length: 200	NA	no
Sterilization Method							
Device Packaged as Sterile	Indicates the medical device is free from viable microorganisms. See ISO/TS 11139.	Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device as it enters Commercial Distribution. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler.	None	Required	Type: Boolean	Yes/No	YES

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Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Requires Sterilization Prior to Use	Indicates that the device requires sterilization prior to use.	Choose Yes/No from the drop down list. The two Sterilization Method questions are independent of each other; this element is designed to capture information about the device before it can safely encounter a patient, regardless of whether the device is single use or reused after reprocessing. These data elements are not designed to capture sterilization procedures executed by the manufacturer or labeler. If answered 'Yes', at least one Sterilization Method (below) must be selected.	None	Required	Type: Boolean	Yes/No	YES

Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
Sterilization Method	Indicates the method(s) of sterilization that can be used for this device prior to device use on the patient.	Choose a value from the drop down LOV. Only applicable if the answer to 'Requires Sterilization Prior to Use' is 'Yes'; otherwise, the LOV will remain inactive. Note that the sterilization method must be applied by the user prior to device use on patient. The Entry LOVs represent the sterilization methods recognized by the CDRH Infection Control Branch. Methods selected should be only those approved for each device by the CDRH Office of Device Evaluation.	Add Delete Edit	Conditionally Required* *if 'Requires Sterilization Prior to Use' is marked 'Yes'	NA	Chlorine Dioxide; Dry Heat; Ethylene Oxide; High Intensity Light or Pulse Light; High-level Disinfectant; Hydrogen Peroxide; Liquid Chemical Steriliation; Microwave Radiation; Moist Heat or Steam; Nitrogen Dioxide; Ozone; Peracetic Acid; Radiation; Sound Waves; Supercritical Carbon Dioxide; Ultraviolet	no

Footnotes

1	**Add** = Addition of new data is allowed; **Delete** = Deletion of entered data is allowed; **Edit** = Editing of entered data is allowed; **None** = NO edit, add, or delete are allowed; **NA** = data element is not able to be changed directly; most are 'auto-populated' fields whose information depends on another data element
2	See 21 CFR 830.310 and 830.340 for required data elements.

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Data Element	Description	Data Entry Notes	Edit Rules After Grace Period [1]	Required in Database? [2]	Data Type & Length [3]	Entry List of Values (LOV)	New DI Trigger
When a GUDID attribute appears in the medical device labeling, the values submitted to the GUDID should match the value in the labeling.							
3	**Alpha** = alpha only; **Num.** = numeric; **Alphanum.** = alphanumeric; **Date Format** = enter as yyyy-mm-dd; **NA** = data elements with a checkbox or LOV that don't require text entry						
4	Most of the information presented here is applicable to GUDID HL7 SPL submissions, but there are some differences pertinent to each submission option. Please refer to the HL7 SPL Implementation package of files for additional details on HL7 SPL xml file submission option.						
^	GUDID data elements that are not released to the public						