**PMCF Determination Worksheet**

This worksheet helps determine whether a medical device requires PMCF. The MDR Annex III Post-market Surveillance Plan requires either a PMCF Plan or a justification as to why a PMCF is not applicable. Use the worksheet to help make the determination. If PMCF is not applicable use the worksheet to document the reasoning and include it in the Annex II and the Annex III documentation.

The factors for consideration below come from two sources.

MEDDEV 2.12/2 Rev. 2 Post Market Clinical Follow-Up Studies – A Guide for Manufacturers and Notified Bodies

IMDRF MDCE WG(PD1)/Nx Post-Market Clinical Follow-Up Studies (Proposed Document)

For each factor below, determine whether it applies (Yes or No) and provide a reason for the response. If any factor applies, then PMCF is applicable.

Alternately, weigh each factor (High, Medium, or Low) and establish a threshold such as one High, or three Medium, or five Low.

| **Section 1 Device Information** | |
| --- | --- |
| *Note: Ensure the information here matches the information in the MDR Annex II(1.1)* | |
| Product or Trade Name |  |
| Model |  |
| General Description of the Device |  |
| Device Class: include the Annex VIII Classification Rule, Paragraph, and Indent |  |
| Basic UDI-DI |  |
| EMDN Code |  |
| MDA/MDN Codes |  |

| **Section 2 Innovation** | |
| --- | --- |
| *The design of the device, the materials, substances, principles of operation, technology, or medical indications are novel*  *Source: MEDDEV 2.12/2 Rev. 2 IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 3 Significant Change** | |
| --- | --- |
| *There is a significant change to the device or intended after completing pre-market clinical evaluation and applying the CE Mark.*  *Source: MEDDEV 2.12/2 Rev. 2* | |
| Response | Applies |
|  |  |

| **Section 4 High Product Related Risk** | |
| --- | --- |
| *There is a high product risk based on design, materials, components, invasiveness, or clinical procedures*  *Source: MEDDEV 2.12/2 Rev. 2* | |
| Response | Applies |
|  |  |

| **Section 5 High Risk Anatomical Location** | |
| --- | --- |
| *The intended use is in a high-risk location such as the central nervous system*  *Source: MEDDEV 2.12/2 Rev. 2 IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 6 High Risk Target Population** | |
| --- | --- |
| *The intended use is in a high-risk target population such pediatric or geriatric*  *Source: MEDDEV 2.12/2 Rev. 2* | |
| Response | Applies |
|  |  |

| **Section 7 Challenges** | |
| --- | --- |
| *There are challenges because of the severity of the disease or its treatment*  *Source: MEDDEV 2.12/2 Rev. 2 IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 8 Clinical Investigation Results** | |
| --- | --- |
| *There are questions about the ability to generalize clinical investigation results from one study population to other populations such as from adults to children*  *Source: MEDDEV 2.12/2 Rev. 2 IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 9 Long-term Safety and Performance** | |
| --- | --- |
| *There are unanswered questions about the long-term safety, performance, or effectiveness of the device*  *Source: MEDDEV 2.12/2 Rev. 2 IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 10 Previous Clinical Investigations** | |
| --- | --- |
| *There are questions about the results from any previous clinical investigation, including adverse events or PMS*  *Source: MEDDEV 2.12/2 Rev. 2* | |
| Response | Applies |
|  |  |

| **Section 11 Unstudied Populations** | |
| --- | --- |
| *Identification of previously unstudied populations that may have a different benefit/risk-ratio*  *Source: MEDDEV 2.12/2 Rev. 2* | |
| Response | Applies |
|  |  |

| **Section 12 More Varied Population** | |
| --- | --- |
| *Identification of larger or more varied patient or user population*  *Source: MEDDEV 2.12/2 Rev. 2* | |
| Response | Applies |
|  |  |

| **Section 13 Other Medical Devices** | |
| --- | --- |
| *Risks identified from the literature or other data sources for similar devices*  *Source: MEDDEV 2.12/2 Rev. 2* | |
| Response | Applies |
|  |  |

| **Section 14 New Information** | |
| --- | --- |
| *New information on safety or performance emerges*  *Source: MEDDEV 2.12/2 Rev. 2 IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 15 Comparable Devices** | |
| --- | --- |
| *Devices based on scientifically well-established technologies and use clinical data or pre-clinical data from comparable devices*  *Source: IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 16 Urgent Market Access** | |
| --- | --- |
| *Public health emergencies, such as a pandemic, may alter the benefit-risk profile*  *Source: IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 17 Rare Anticipated Serious Incidents** | |
| --- | --- |
| *Rare anticipated serious incidents may require a dataset larger than typically available for a pre-market study*  *Source: IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |

| **Section 18 Risk Reduction Effectiveness** | |
| --- | --- |
| *Confirmation of the effectiveness of an EN ISO 14971:2019 risk reduction measure*  *Source: IMDRF MDCE WG(PD1)/Nx* | |
| Response | Applies |
|  |  |