**Change Assessment**

**Example 2**

This adapts the Regulatory Change Assessment (Example 2) from the main guidance. However, it uses a different method to document the paths through the flowcharts. It also uses different questions to describe the device.

**Product Name:** Cardiopulmonary Bypass (CPB) Cannula

**Date of the Change Assessment:** January 20, 2017

**Brand Name:** Ultra Cannula

**Version or Model Number:** Model 1 and Model 2

**Primary DI Number:** 83MPQ17809YTRE and 83MPQ17809YTSF

**Description of the Device:**

Cardiopulmonary Bypass Cannula is intended to cannulate the vessels, perfuse the coronary arteries, and interconnect the catheters and cannulas with an oxygenator. The current design uses a 304 stainless steel guidewire with a coating composed of material X; the tips of the guidewire are partially uncoated. See design specifications at Document 18-XXXX.

**If this is a software device, what is the Level of Concern before the change?** N/A, not a software device

**Description of the Change:**

The change is to remove the coating from the guidewire. Previously, the tips were uncoated, but now the entire guidewire will be uncoated. This change applies to models 1 and 2. These models were originally cleared in K10xxxx. The uncoated guidewire will continue to be made of 304 stainless steel. The replacement and current guidewires are identical in design, performance, and materials, with the exception of the coating.

The current guidewire was chosen originally because it was from our current guidewire supplier (which supplies guidewires for other cannulas we manufacture), met the dimensional specifications, and was cost-effective. The coating on the original cannula was not a specific design feature that was required for the design, although it may contribute to longevity of the guidewire and enhances lubricity.

The proposed change will remove the coating, which will expose the stainless steel along the entire length of the guidewire. This change does not introduce any new blood-contacting materials as the current guidewire tip is uncoated, and was tested for biocompatibility in the most recently cleared 510(k). We previously marketed a cannula with an uncoated 304 stainless steel guidewire, cleared in K08xxxx (see DHF XXXX).

Removing the coating from the guidewire will also result in a small change to the diameter of the guidewire due to the lack of the coating.

We have confirmed that the Type 304 material used for the uncoated guidewire is from the same supplier as we have used previously (see Communication 11/7/19-XXXX from supplier), and there have been no issues with rusting (which could introduce embolic particles during device use). In addition, we have confirmed that there are no manufacturing residuals on the surface of the Type 304 stainless steel guidewire that would be available to the patient now that the guidewire is no longer coated (see Memo 19-XXXX).

**Reason for Change:** The coated guidewire has been discontinued by the supplier.

**501(k) Number of the most recently cleared version of the device:** Originally cleared in K10xxxx

**Identify all device changes under §820.30(i) since the most recent 510(k):** A change in labelling layout under ECO 12-XXXX

**Identify all device changes under §820.70(b) since the most recent 510(k):** No changes under §820.70(b).

**Compare the modified device to most recently cleared device. Include all changes that did not require a new 510(k):** The modified device includes an updated labeling layout and removal of the guidewire coating.

**Main Flowchart Decisions**

Each box below documents the decision on the main flowchart, including software. If a flowchart applies, document the decision path to the conclusion (Documentation or New 510(k))

| Question | Yes/No | Decision, Chart, or N/A |
| --- | --- | --- |
| Does the change significantly improve the safety of the device? | No | N/A |
| Does the change significantly improve the effectiveness of the device? | No | N/A |
| Is the device an IVD? | No |  |
| Does the change involve a software change? | No |  |
| Is this a labeling change? | No |  |
| Is this a technology, engineering, or performance change? | Yes | Flowchart B |
| Is this a materials change? | Yes | Flowchart C |

**Flowchart B Analysis**

| # | Question | Yes/No | Reason for the decision | Next |
| --- | --- | --- | --- | --- |
| B1 | Is the device an IVD? | No | The device does not meet the definition of an IVD. | B2 |
| B2 | Is it a control mechanism, operating principle, or energy type change? | No | The change doesn’t affect any of these factors. | B3 |
| B3 | Is it a change in sterilization, cleaning, or disinfection? | No | The change doesn’t affect any of those factors? | B4 |
| B4 | Is there a change in packaging or expiration dating? | No | The change doesn’t affect any of those factors? | B5 |
| B5 | Is it any other change in design (*e.g.,* dimensions, performance specifications, wireless communication, components or accessories, or the patient/user interface)? | Yes | There are two changes. One change removes the coating on the guidewire. One change affects the diameter of the guidewire. | B5.1 |
| B5.1 | Does the change significantly affect the use of the device? | No | The lack of coating and the small dimensional change are not expected to affect the use of the device. | B5.2 |
| B5.2 | Does a risk-based assessment of the changed device identify any new risks or significantly modified existing risks? | No | See full risk-based assessment in Document 20-XXXX.Dimensional change: it is unlikely that the small reduction in guidewire diameter could affect safety or effectiveness. Decreasing the diameter of the guidewire would not be expected to hinder the interaction between the guidewire, introducer, and cannula, and it would not be expected to reduce the strength of the guidewire, as the coating did not improve the strength of the wire and the wire itself remains unchanged.Removal of the coating: it is unlikely, but possible, that the removal of the coating could impact the way the guidewire interacts with the introducer and cannula. We have previously obtained clearance for cannulas with uncoated stainless steel guidewires, however, which did not have markedly different performance (see DHF XXXX). This suggests that the significance of this change is low.We have determined there are no new or significantly modified risks due to this change. | B5.3 |
| B5.3 | Are clinical data necessary to evaluate safety or effectiveness for purposes of design validation? | No | Clinical data is not necessary for design validation. | B5.4 |
| B5.4 | Do design verification or design validation activities produce any unexpected issues of safety or effectiveness? | No | See verification and validation testing report in Document 20-YYYY, conducted after the risk-based assessment. Functional testing evaluated the interaction between the guidewire, introducer, and cannula to verify that the uncoated guidewire did not affect device performance. There were no unexpected issues of safety or effectiveness. | Document |

**Flowchart C Analysis**

| # | Question | Yes/No | Reason for the decision | Next |
| --- | --- | --- | --- | --- |
| C1 | Is the device an IVD? | No | The device does not meet the definition of an IVD. | C2 |
| C2 | Is this a change in material type, material formulation, chemical composition, or the material’s processing? | Yes | The coating material will no longer be used. | C3 |
| C3 | Will the changed material directly or indirectly contact body tissues or fluids? | Yes | The modified guidewire can contact circulating blood. | C4 |
| C4 | Does a risk assessment identify any new or increased biocompatibility concerns? | No | The tips of the current guidewire are uncoated, so there is no new material here to create new biocompatibility concerns. The removal of the coating material is not expected to have a biocompatibility impact as the processing is unlikely to leave residuals that were previously masked by the coating. In addition, we have previously marketed cleared cannulas with uncoated stainless steel guidewires, which passed biocompatibility testing (see DHF XXXX). The source of the stainless steel used to manufacture these guidewires has not changed, and we have had no issues with rusting components, so embolic risk is not a concern. | C5 |
| C5 | Could the change affect the device’s performance specification? | Yes | See the design change analysis above. | B5 |
| B5 | See the analysis starting with B5 in Flowchart B documentation. |