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| **PURPOSE** | | | | | | |
| *<Directions for use: This is a template to guide design and regulatory change assessments. Replace highlighted text with relevant document names or numbers. Remove these directions and other blue example text prior to use of the template.>* | | | | | | |
| **Applicable Regulatory Documentation** | | | | | | |
| *< 510(k) (KXXXXXX) for medical device number XXX.>* | | | | | | |
| **SCOPE** | | | | | | |
| *<The detailed scopes, purpose and impacts of the changes are individually itemized in the table below and are also referenced in the Design and Development Plan DDP# XXX. This evaluation will delineate elements of the devices that are potentially affected by the changes and in context are appropriate to address basic considerations for the significant change requirements. Consideration is given to the impact of the changes individually as well as the cumulative effect of the changes as a whole.>* | | | | | | |
| **TABLE 1. LIST OF CHANGES** | | | | | | |
| **Change** | **Applicable to P/N:** | **Change Description** | **Purpose of Change** | | | **Change Impact/Assessment** |
|  |  |  |  | | | *<Use Table 2 below, as appropriate and report results/conclusions here.>* |
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| **TABLE 2. CHECKLIST TO ASSESS CHANGE** | | | | | | |
| **Change (Material, Component, Part, Device)** | | | | **Yes** | **No** | **Comments** |
| Does change impact existing product drawings, schematics, diagrams, etc.? | | | |  |  |  |
| Does change impact an existing Bill of Materials? | | | |  |  |  |
| Does change impact existing assembly or testing procedures? | | | |  |  |  |
| Does change impact existing product test results? | | | |  |  |  |
| Does change impact existing operations or maintenance instructions? | | | |  |  |  |
| Does change impact existing manufacturing processes? | | | |  |  |  |
| Does change impact existing product labels, i.e. Caution, Warning, Certification, etc.? | | | |  |  |  |
| Does change impact existing components, parts, or materials in inventory? | | | |  |  |  |
| Does change impact an existing product qualification or certification? | | | |  |  |  |
| Does change require notification to regulatory agency, including NRC? | | | |  |  |  |

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| **Is the product marketed in the USA?**  **Yes**  **No** If yes, also use this section below for the assessment. | | | | |
| **Considerations for 510(k)**  This evaluation delineates which features are potentially affected by the changes and identifies which decision flowcharts are applicable to fully assess considerations for filing a new 510(k).  Using the context and answers provided in the sections above, the changes were evaluated against the items outlined in the FDA guidance document “[**Deciding When to Submit a 510(k) for a Change to an Existing Device**](https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm514771.pdf)**”** to determine if the changes substantially affect the current 510(k) for the product and if an update to the file in process is needed. | | | | |
| **MAIN FLOWCHART** | | | | |
| **Question** | **Answer** | | | **Go to Flowchart?** |
| Is the change made with the intent to significantly improve the safety or effectiveness of the device? |  | | | If yes, submit new 510(k) |
| 🡫 **If no** |  | | | |
| Is it a labeling change? |  | | | If yes, go to flowchart A |
| 🡫 **If no** |  | | | |
| Is it a technology, engineering, or performance change? |  | | | If yes, go to flowchart B |
| 🡫 **If no** |  | | | |
| Is it a material change? |  | | | If yes, go to flowchart C |
| 🡫 **If no**  Document to file |  | | |  |
| **Flowchart A – Is it a labeling change?** | | | | |
| **Question** | **Yes** | **No** | **Comments** | |
| **A1.** Is it a change in the indications for use statement? | Go to A1.1 | Go to A2 |  | |
| * **A1.1** Is it a change from a device labeled for single use only to a device labeled as reusable? | Submit 510(k) | Go to A1.2 |  | |
| * **A1.2** Is it a change from Rx to over the counter OTC use? | Submit 510(k) | Go to A1.3 |  | |
| * **A1.3** Is it a change to the device name or to solely improve readability or clarity? | Document to file | Go to A1.4 |  | |
| * **A1.4** Does the change describe a new disease, condition, or patient population that the device is intended in diagnosing, treating, preventing, curing, or mitigating? | Submit 510(k) | Go to A1.5 |  | |
| * **A1.5** Does a risk-based assessment identify any new risks or significantly modified existing risks? | Submit 510(k) | Document to file |  | |
| **A2.** Does the change add or delete a contraindication? | Submit 510(k)  (if adding a contraindication, submit CBE 510(k)) | Go to A3 |  | |
| **A3.** Is it a change in the warnings or precautions? | Go to A1.1 | Go to A4 |  | |
| **A4.** Could it affect the directions for use? | Go to A1.1 | Document to file |  | |
| **Flowchart B – Is it a technology, engineering, or performance change?** | | | | |
| **Question** | **Yes** | **No** | **Comments** | |
| **B2.** Is it a control mechanism, operating principle, or energy type change? | Submit 510(k) | Go to B3 |  | |
| **B3.** Is it a change in sterilization, cleaning, or disinfection? | Go to B3.1 | Go to B4 |  | |
| * **B3.1** Is it a change to a Cat. B or novel method, does it lower the SAL, or is it a change to how the device is provided? | Submit 510(k) | Go to B3.2 |  | |
| * **B3.2** Could the change significantly affect performance/biocompatibility? | Submit 510(k) | Document to file |  | |
| **B4.** Is there a change in packaging or expiration dating? | Go to B4.1 | Go to B5 |  | |
| * **B4.1** Is the same method or protocol, described in previous 510(k), used to support change? | Document to file | Submit 510(k) |  | |
| **B5.** Is it any other change in design (e.g., dimensions, performance specifications, wireless communications, components or accessories, patient/user interface)? | Go to B5.1 | Document to file |  | |
| * **B5.1** Does the change significantly affect the use of device? | Submit 510(k) | Go to B5.2 |  | |
| * **B5.2** Does a risk assessment identify any new or significantly modified risks? | Submit 510(k) | Go to B5.3 |  | |
| * **B5.3** Is clinical data necessary? | Submit 510(k) | Go to B5.4 |  | |
| * **B5.4** Any unexpected issues from V&V activities? | Submit 510(k) | Document to file |  | |
| **Flowchart C – Is it a material change?** | | | | |
| **Question** | **Yes** | **No** | **Comments** | |
| **C2.** Change in material type, formulation, chemical composition, or the material’s processing? | Go to C3 | Document to file |  | |
| * **C3.** Will the changed material directly or indirectly contact body tissues or fluids? | Go to C4 | Go to C5 |  | |
| * **C4.** Does a risk assessment identify any new or increased biocompatibility concerns? | Go to C4.1 | Go to C5 |  | |
| * + **C4.1** Has the manufacturer used the same material in a similar legally marketed device (including formulation, processing, type and duration of contact, etc.)? | Go to C5 | Submit 510(k) |  | |
| * **C5.** Could the changed affect performance specifications? | Go to B5 | Document to file |  | |

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| **Distinguishing Medical Device Recalls from Medical Device Enhancements**  Further evaluation for the need to report the device change under 21 CFR 806 of the design change is given to the considerations outlined in FDA guidance “[**Distinguishing Medical Device Recalls from Medical Device Enhancements**](https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM418469.pdf).” | | |
| **Question** | **Answer** | **Action** |
| Are the changes intended to resolve a failure to meet specifications or failure of the device to meet specifications or failure of the device to perform as represented? |  |  |
| Is the labeling for the device to which you are considering making changes false or misleading, does it fail to bear adequate directions for use, or does it otherwise violate the FD&C Act or FDA regulations? |  |  |
| Is the company otherwise out of compliance with FDA regulations? Is the change made to correct or remove a violative marketed device to bring it into compliance with FDA laws? |  |  |

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| **CONCLUSION** | | |
| *<The changes were reviewed to determine the impact on the safety and effectiveness of P/N: XXX. Based on the evaluation and assessment above, it may be concluded that the changes above are (or are not) significant and that they will (or will not) adversely affect the performance, essential requirements, intended use, operating principal, safety, quality and effectiveness of the finished device. Further, these changes are not related to a recall or field correction. Testing and verification activities were conducted to ensure that the modified device design meets all design input requirements. Therefore, the following was concluded:*   * ***FDA*** *–* | | |
| **ATTACHMENTS** | | |
| *<Attachment 1: Title>* | | |
| **ASSESSMENT APPROVAL** | | |
| Assessment Conducted by (Name and Title): | Date: | *Signature*: |
| Independent Assessment Review Conducted by (Name and Title): | Date: | *Signature*: |