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| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **1. Engineering Change Description** | | | | | **ECO #:** | |  | |
| **Product:** | |  | **Product Model #:** |  | | | | |
| **Changes Request By:** | |  | **Date:** |  | | | | |
| **Type(s) of Change:** | | Product Design  Software Design  Manufacturing Process  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **Description of Changes:** | | **(Description of changes and rationale. Attach additional information as necessary)** | | | | | | |
| **2. Impact of Changes** | | | | | | | | |
| **Impact to the Medical Device:** | | **(Description of the impact of the changes to the medical device and its intended use. Includes evaluation of Function, Performance, Usability, Safety, and the Risk Management File)** | | | | | | |
| **Impact to Regulatory Requirements** | | **(Description of the Regulatory impacts of the change such as: 510(k) submissions, Regulatory Authority Notification, etc.)** | | | | | | |
| **Impact to Existing Product:** | | **(Description of the impact of the changes to existing product and product already being manufactured.)** | | | | | | |
| **Disposition of Inventory** | | Not Applicable  Scrap  Rework  Use to Completion  Other:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | |
| **Impact to Validations:** | | **(List of Verifications, Validations, and Qualifications that are impacted by the change and the associated rationale. Attach additional information as necessary)** | | | | | | |
| **Impact to Training** | | **(List of the job functions that require training regarding the change)** | | | | | | |
| **Impacted Documents: Title** | | | | | **Doc ID** | **Rev** | |
|  | | | | |  |  | |
|  | | | | |  |  | |
|  | | | | |  |  | |
| **3. Reviews** | | | | | | | | |
| **Sales and**  **Marketing** | Comments: | | | | | | | |
| Marketing Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **Engineering** | Comments: | | | | | | | |
| Engineering Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **Operations** | Comments: | | | | | | | |
| Operations Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **Quality**  **and Regulatory** | Comments: | | | | | | | |
| Quality Representative: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | |
| **4. ECO Closure Review** | | | | | | | | |
| **Quality Representative:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ | | | | | | | | |