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| 1. **IDENTIFICATION OF THE ISSUE** | |
| **Customer Complaint or CAPA #:**  **(if applicable)** |  |
| **Product Information** | |
| **Product Code:** |  |
| **Model:** |  |
| **Device Name:** |  |
| **Lot/Serial Numbers:** |  |
| **Marketing Status:** | *(Include 510(k) or PMA Number, Specify if Class I Exempt from 510(k))* |
| **Manufacturer/Recall Firm Address:** |  |
| **Product Description (Include Intended Use From Labeling):** |  |
| **Issue Information** | |
| **Brief description of the issue/problem and how it was identified:** |  |
| **Affected Patient/User Population:** | *List the types of patients/users who may be affected by the issue. Identify those at highest risk (e.g. neonates, elderly, pregnant women, patients with heart disease, etc.).* |
| **HHE Owner (Name/Function):** |  |
| **HHE Contributors (Name/Function):** | *Include those with an understanding of the function of the device (i.e. design engineers), and of the application of the device (i.e. clinical experts).* |

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| 1. **ANALYZE POST RELEASE HEALTH RISK ASSOCIATED WITH AFFECTED UNITS**   **Note:** Assess the risk as if no corrective action will be taken and all affected devices will remain in the marketplace. | | | |
| **Identification of the Individual Hazard(s)** | | | |
| **Hazard Category:** | *Describe the source/ potential source of harm (e.g., electrical, mechanical, misdiagnosis, etc.)* | | |
| **Hazard Cause** | *Describe the cause (e.g., software defect, component failure, poor usability, etc.) of the hazard in detail. Identify whether the hazard or hazardous situation happens under normal use, use error, or misuse conditions.* | | |
| **Hazardous Situation** | *Describe the circumstance in which people are exposed to the hazard.* | | |
| **Estimation of Severity** | | | |
| **Description of reported and/or potential harm:** | *Describe in detail the harm or damage to the health of any person (reported and potential) (e.g. broken bone, death). In case of injuries, describe whether injuries are irreversible, temporary, need follow-up treatment, etc. Consider the severity of harm for segments of the population most at risk (infants, elderly, pregnant women, critically ill patients, etc.).* | | |
| **Estimation of Severity of Harm:** | **Check One** | **Severity Rank** | **Example** |
| *\* Severity Levels 4 and 3 are “serious adverse health consequences” per FDA’s CDRH Health Hazard Evaluation Form Version 3-1 01/12/2007. Severity Levels 2 and 1 are not serious adverse health consequences per FDA’s HHE Form.* |  | 4 | Directly results in death |
|  | 3 | Results in serious injury: life-threatening, or permanent impairment or necessitates medical intervention to preclude permanent impairment |
|  | 2 | Results in moderate injury: temporary impairment, or self-limiting illness |
|  | 1 | Results in less than moderate or no injury |
| Comments about severity of harm rationale: *If no additional comments are needed to further explain the estimation of severity, enter “None.”* | | | |

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| 1. **ESTIMATION OF PROBABILITY OF HARM RESULTING FROM AFFECTED UNITS** | | | |
| **Estimated quantity of affected devices (# in field, # in factory, # in distribution centers, etc.):** | | |  |
| **Number and type of injuries/number of deaths attributed to the problem with the device (if any):** | | |  |
| **Describe the factor(s) that need to occur to create the hazardous situation (reasonably foreseeable sequence or combination of events):** | | |  |
| **Factors that might mitigate risk (e.g., safety mechanisms present in the design, instructions for use, current label warnings, etc.):** | | |  |
| **Would a user detect the hazardous situation prior to occurrence of harm? If so, describe how:** | | |  |
| Considering the factors above, assess the probability that use of, or exposure to, the affected devices will cause future harm during the product’s lifetime. Consider segments of the population most at risk (e.g. infants, elderly, pregnant women, critically ill patients, etc.). | | | |
| **Check One** | **Probability Rank** | **Example of probability of harm** | |
|  | 4 | Occurs ‘every time’\* | |
|  | 3 | Good chance to occur; considerable certainty to occur; ‘reasonable probability’\* | |
|  | 2 | Expected to occur from time to time (e.g., no clear trend); rarely occurring; ‘remote’\* | |
|  | 1 | Not expected to occur | |
|  | 0 | Inconceivable; not possible | |
| \* Corresponds with probability levels set forth in FDA’s CDRH HHE Form Version 3-1 01/12/2007. | | | |
| **Note: If harm has already occurred as a result of the issue under review,** then:  Probability level zero (0) and one (1) can only be used if the investigation shows the harm was the result of an isolated incident and no other units are likely to be affected; a detailed rationale for why harm is not likely to occur again in the future must be provided. | | | |
| Comments about probability of harm rationale: *If no additional comments are needed to further explain the estimation of probability of harm, enter “None.”* | | | |

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| 1. **HEALTH RISK ASSESSMENT CONCLUSION** | | | | |
| **Probability** | **Severity** | | | |
| **1** | **2** | **3** | **4** |
| **4** | Unacceptable | Unacceptable | Unacceptable | Unacceptable |
| **3** | Acceptable | Unacceptable | Unacceptable | Unacceptable |
| **2** | Acceptable | Further Analysis Required1) | Unacceptable | Unacceptable |
| **1** | Acceptable | Acceptable | Further Analysis Required1) | Unacceptable |
| **0** | Acceptable | Acceptable | Acceptable | Acceptable |
| 1) If the results of a risk evaluation fall into one of these two cells (3x1 or 2x2), then a rationale with sufficient details (such as a risk/benefit analysis) must be documented in section C below for the risk to be considered acceptable. | | | | |
| **Notes:** The original premarket rationale and or risk/benefit analysis may be reused if still applicable as the evaluation to justify an acceptable risk.  The above Risk Table helps assess whether the risk is acceptable or not; however, reviewer/approvers of this document make the final determination. | | | | |
| **Document the results of the Health Hazard Evaluation for each hazardous situation under review:** | | Severity:\_\_\_\_/ Probability: \_\_\_\_\_ = \_\_\_\_\_\_\_\_ (acceptable/ unacceptable) | | |
| **If the risk of the individual hazardous situation is acceptable, review the Risk Management Summary (RMS) and consider combined impact of all the individual risks to evaluate whether overall residual risk of the device is still acceptable. Is the summary of all the risks acceptable or not acceptable?** | |  | | |
| **Any additional information (if applicable):** | |  | | |
| **Health Hazard Evaluation Conclusion:** | | *(Explain determination as to acceptable or unacceptable health risk)* | | |

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| 1. **OUTCOME APPROVALS** |
| **Prepared By:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name and Title  **QA/RA Management:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name and Title  **Additional Approver(s) identified by QA/RA, if applicable:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name and Title  **Approved By President or CEO:**  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Signature Date  \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_  Print Name and Title |