|  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **Complaint #:** | | | | | | | | ***<Enter Complaint #>*** | |
| **Section 1: General Information** *(To be completed by GT Medical)* | | | | | | | | | |
| Date Complaint Received (YYYY-MM-DD): | | | | | | | Written Complaint *(attach complaint)* | | |
| Complaint Received by: | | Title: | | | | | Verbal Complaint | | |
| Department: | | Phone/ext.: | | | | | Electronic Complaint *(attach complaint)* | | |
| Email: | | | | | | | Returned Product | | |
| **Complainant Information** | | | | | | **Device Information** | | | |
| Name: | | | | | | Device Name: | | | Model/Version Number: |
| Facility Name: | | | | | | Serial/Lot Number: | | | Catalog Number: |
| Street: | | | | | | UDI(s): | | | |
| City: | State: | | Zip: | | | Oher Information: | | | |
| Telephone/Ext.: | Fax: | | | | |
| Email: | | | | | |
| **Complaint Information** | | | | | | | | | |
| 1. Date of Incident | | | |  | | | | | |
| 1. Where was product purchased (if complainant is end user)? | | | |  | | | | | |
| 1. Is there any evidence of misuse or alteration by the customer? | | | | Yes *(If Yes, explain in complaint description)*  No | | | | | |
| 1. Is device still being used? | | | | Yes  No  Unknown | | | | | |
| 1. Removed part in GT Medical’s posession? | | | | Yes  No  Expected to tbe returned | | | | | |
| 1. Can complainant provide a picture of device? | | | | Yes *(If Yes, attach picture)*  No | | | | | |
| 1. Was device being used for treatment during event? | | | | Yes  No  Unknown | | | | | |
| 1. Was anyone injured (even slightly)? | | | | Yes *(If Yes, explain in Details section.)*  No (*If no, skip to question 11.)* | | | | | |
| 1. Was there any property damage other than device involved? | | | | Yes *(If Yes, explain)*  No | | | | | |
| 1. Is there indication that the user submitted a report to the FDA? | | | | Yes *(If Yes, request a copy and submit with this form)*  No | | | | | |
| 1. Supplies or Equipment involved in the complaint: | | | | Part Number and Name:  Serial/Lot #::  UDI(s): | | | | | |
| Relevant Patient History, including pre-existing medical conditions if known (DO NOT INCLUDE PERSONAL HEALTH INFORMATION (PHI): | | | | | | | | | |
| **Details of Complaint** *(attach supporting materials and any correspondence with complainant)* | | | | | | | | | |
|  | | | | | | | | | |
| Recipient Name: | | | | | Date: | | | | |

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
| **Section 2: Complaint Evaluation** *(To be completed by GT Medical)* | | | | |
| Type of Complaint *(check all that apply)*: | | | | |
| Product Performance | Product Safety | | Product Effectiveness | Product Appearance |
| Product Identity | ☐ Other: | |  |  |
|  |  | |  |  |
| **Regulatory Reporting Decision Tree**: Complete the flow on the following page to document determination of regulatory reporting requirements.  **Reportable?**  ☐ No  ☐ Yes *(If Yes, attach a copy of the applicable regulatory reports.)*  **Containment:** With current knowledge and reportability evaluation, are containment actions applicable?  ☐ No containment actions applicable.  ☐ Recall (see SOP-003 Complaint Handling, Reporting, and Recall)  ☐ Other, describe.  **Complaint Log:** Complaint Log F-003B has been reviewed for other relevant or similar events. Reference complaint numbers and make notes as necessary to describe relevance:  **Complaint Action Required:**  ☐ Investigation (*If yes, fill “Complaint Investigation” section below.)*  ☐ No Investigation *(If no, provide justification below.)* | | | | |
| Justification: | | | | |
| *Completed by:* | | *Signature and Date:* | | |

**Regulatory Reporting Decision Tree**



|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Review Performed by: | | | | | | Signature and Date: | |
|  | | | | | | | |
| **Section 3: Complaint Investigation** *(to be completed by IsoRay***)** | | | | | | | |
| **Investigation Summary/Results** *(Attach Supporting Material, e.g. engineering reports, HHE form, etc. as necessary.)*:    **Root cause:** | | | | | | | |
| **Conclusion:** | | | | | | | |
| Product conformed to specifications: | | | | Yes | No | | Could not confirm |
| **Risk Management:** Does this event or action need to be added to the Risk Management File for this product?  Yes, the product’s Risk Management File will be updated with a corresponding Hazard Sit. ID#(s)  No, This event is captured by the Risk Management File: Hazardous Situation ID / Reference: | | | | | | | |
| **Containment:** Are containment actions necessary for other nonconforming or potentially nonconforming product?  Yes, product has not been released. Document all actions taken :  Yes, and product has been released to customer. Notify GT Medical immediately (same day).  No Comments: | | | | | | | |
| Completed by: | | | Signature and Date: | | | | |
| **IsoRay to return this form to GT Medical for completion** | | | | | | | |
| **Section 4: Corrective and/or Preventive Action (***To be completed by GT Medical***)** | | | | | | | |
| **Corrective or Preventive Action:** Are actions required to address a nonconformance or potential nonconformance?  Note: Documentation of corrective action required for nonconformances related to product safety / efficacy.  Yes: A corrective/preventive action should be initiated.  Provide SCAR # (see SOP-002):  Date of Closure of SCAR, if required:  No: Data does not suggest an adverse system trend.  Provide rationale: | | | | | | | |
| Completed by: | | | Signature and Date: | | | | |
| **Section 5: Complaint Closure** | | | | | | | |
| Complaint Closed | Date: | *Quality Assurance (Signature and Date):* | | | | | |