

Complaint  Removal # \_\_\_\_\_  
(check one)

Device Name \_\_\_\_\_

Catalog Number \_\_\_\_\_ Lot Number \_\_\_\_\_

Salesman \_\_\_\_\_

Name of Complainant \_\_\_\_\_ Phone No. \_\_\_\_\_

Complainant Address \_\_\_\_\_

Complaint Received by \_\_\_\_\_

Title \_\_\_\_\_ Date Received \_\_\_\_\_

By:  Visit  Phone  Letter  E-mail  Other

**COMPLAINT/REMOVAL ABOUT**

Sterility \_\_\_\_\_

Particulate Matter Type \_\_\_\_\_ Location \_\_\_\_\_

Defect \_\_\_\_\_

Packaging \_\_\_\_\_

Labeling \_\_\_\_\_

Patient Death \_\_\_\_\_

Patient Injury \_\_\_\_\_

Product Malfunction \_\_\_\_\_

Other (specify) \_\_\_\_\_



Customer  
Complaint/Removal  
Form

DCN# 0072

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Comments/Description of Event \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

**ATTACHMENTS**  Implicated Sample  Associated Sample  Letter

Received By \_\_\_\_\_ Date \_\_\_\_\_

Assigned To \_\_\_\_\_ Response Due \_\_\_\_\_

Instructions \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Distribution:  Administration  Engineering  Quality/Regulatory  Sales

**ASSIGNEE EVALUATION**

Date(s) Evaluation Performed \_\_\_\_\_

Evaluation Results \_\_\_\_\_

Copy of Evaluation attached

**CONCLUSIONS**

- Device Defective       Device Failed to Meet Specifications       Improper Use
- Shipping Damage       Repair Request
- Other (specify) \_\_\_\_\_

**ACTION/REPLY TO COMPLAINT/REMOVAL**

None. Reason for no action \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Recalled: FDA phoned on-Date \_\_\_\_\_ Spoke to \_\_\_\_\_

Complaint Committee Informed on- Date \_\_\_\_\_

Replaced  Repaired  Credited  Letter Sent  Sales Follow Up

No Reply (reason) \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

***(Complete FRM-854-01 MDR Checklist before completing the section below)***

MDR Filed. Date \_\_\_\_\_ MDR# \_\_\_\_\_  
 MDR NOT Filed.

Notes:

**FINAL DISPOSITION**

\_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_

Reviewed by: Quality/Regulatory \_\_\_\_\_ Date \_\_\_\_\_

If Requested: Engineering \_\_\_\_\_ Date \_\_\_\_\_