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Class 2 Device Recall Implant Direct, INTERACTIVE HEALING COLLAR

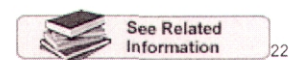


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Class 2 Device Recall Implant Direct, INTERACTIVE HEALING COLLAR



| | |
|---|--|
| Date Initiated by Firm | January 23, 2018 |
| Create Date | February 06, 2018 |
| Recall Status ¹ | Open ³ , Classified |
| Recall Number | Z-0539-2018 |
| Recall Event ID | 78917 ²³ |
| 510(K)Number | K130572 ²⁴ |
| Product Classification | Abutment, implant, dental, endosseous ²⁵ - Product Code NHA ²⁶ |
| Product | Implant Direct, INTERACTIVE HEALING COLLAR, PART NUMBER 6530-15, 5.0mmL: 3.0mmD Platform |
| Code Information | Lot Number 104203 |
| Recalling Firm/Manufacturer | Implant Direct Sybron Manufacturing, LLC 3050 E Hillcrest Dr Westlake Village CA 91362-3171 |
| For Additional Information Contact | Customer Care Team 818-444-3300 Ext. 3323 |
| Manufacturer Reason for Recall | InterActive Healing Collar, Lot Number 104203, labeled as sterile with distributed prior to being sterilized. |
| FDA Determined Cause ² | Process control |
| Action | The firm initiated their recall on 01/23/2018 by letter. the recall notices requested the following actions by the distributors: "1. Please review your inventory for the affected product. 2. Please complete and return the Acknowledgement and Recall Return Form with the affected product, if available, within 48 hours. 3. If you are an authorized Implant Direct Sybron Manufacturing distributor, we request that you identify those customers that may have been shipped the affected product lot and contact these customers to inform them of this issue within fortyeight (48) hours of receipt of this notification in order to provide the customers with replacement product." The letter disseminated to the physician requested the following actions: "1. Please review your inventory for the affected product. 2. Please complete and return the Acknowledgement and Recall Return Form with the affected product, if available, within 48 hours." |
| Quantity in Commerce | 55 units |
| Distribution | CO, SC, IA, NJ, FL, CA, VA, ID, Netherlands |
| Total Product Life Cycle | TPLC Device Report ²⁷ |

¹ A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA identifies a violation and classifies the action as a recall, and it is updated for a final time when the recall is terminated.