FDA

Class 2 Device Recall Implant Direct, INTERACTIVE HEALING COLLAR

See Related Information[22]

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.*