Class 2 Device Recall Cannulated Drill bit 2.0mm and 2.6 mm

See Related Information 22

Date Initiated by Firm	December 22, 2016
Create Date	January 28, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1113-2017
Recall Event ID	76156[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	Cannulated Drill bit 2.0mm and 2.6 mm; Used in conjunction with the Flower Bone Screw Set.
Code Information	Device Listing: D267957
Recalling Firm/ Manufacturer	Flower Orthopedics Corporation 100 Witmer Rd Ste 280 Horsham PA 19044-2647
For Additional Information Contact	215-394-8903
Manufacturer Reason for Recall	The product is being recalled due to incidence and reports of the product breaking during surgery.
FDA Determined Cause [2]	Device Design
Action	Flower Orthopedics mailed a letter to customers on December 22, 2016 making them aware of the issue. Customers were asked to return the affected product and to report if any adverse effects resulted from its use.
Distribution	Distributed throughout the United States
Total Product Life Cycle	TPLC Device Report[26]

[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. Learn more about medical device recalls[27].
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
[3] The manufacturer has initiated the recall and not all products have been corrected or removed. This record will be updated as the status changes.

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