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

**Date Initiated by Firm**: December 22, 2016  
**Create Date**: January 28, 2017  
**Recall Status**: Open, Classified  
**Recall Number**: Z-1113-2017  
**Recall Event ID**: 7615623  
**Product Classification**: Orthopedic manual surgical instrument - Product Code LXH  
**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**: 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  

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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](#).  
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.

**Links on this page:**  
3. [http://www.fda.gov/default.htm](http://www.fda.gov/default.htm)