Class 2 Device Recall Exactech GPS Total Shoulder Application 3.2mm Vix Bit

Date Initiated by Firm: July 11, 2017
Date Posted: January 18, 2018
Recall Status: Open, Classified
Recall Number: Z-0503-2018
Recall Event ID: 78064
Product Classification: Orthopedic stereotaxic instrument - Product Code OLO
Product: Exactech GPS Total Shoulder Application 3.2mm Vix Bit Orthopedic surgical tool
Code Information: Catalog No. 531-15-08. Lot No. 75296003, 80129003, 81327001
Recalling Firm/Manufacturer: Exactech, Inc.
2320 NW 66th Ct
Gainesville FL 32653-1630
For Additional Information Contact: Kaya Davis
800-392-2832
Manufacturer Reason for Recall: Vix Bit may fracture during use.
FDA Determined Cause: Nonconforming Material/Component
Action: Customers were notified on approximately 07/11/2017. Instructions included cease distribution of the affected product, notify customers if further distributed, identify and quarantine any product in inventory and complete and return the Recall Inventory Response Form. For further questions, please call (800) 392-2832.

Quantity in Commerce: 41 devices
Distribution: Worldwide Distribution: US states of Florida and California, Australia, France, Spain, and United Kingdom.

Total Product Life Cycle: TPLC Device Report

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.

510(K) Database: 510(K)s with Product Code = OLO and Original Applicant = Blue Ortho

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=158599
2/19/2018