FDA

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

See Related Information[22]

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[1]	Open[3], Classified
Recall Number	Z-0603-2018
Recall Event ID	78064[23]
510(K)Number	K162567[24]
Product Classification	Orthopedic stereotaxic instrument[25] - **Product Code** OLO[26]
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 [2]	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[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. Learn more about medical device recalls[28].
[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[29]