



U.S. DEPARTMENT OF HEALTH & HUMAN SERVICES  
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**Class 2 Device Recall Exactech GPS Total Shoulder Application 3.2mm Vix Bit**

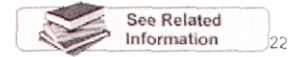


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**Class 2 Device Recall Exactech  
 GPS Total Shoulder Application  
 3.2mm Vix Bit**



<b>Date Initiated by Firm</b>	July 11, 2017
<b>Date Posted</b>	January 18, 2018
<b>Recall Status</b> <sup>1</sup>	Open <sup>3</sup> , Classified
<b>Recall Number</b>	Z-0603-2018
<b>Recall Event ID</b>	<a href="#">78064</a> <sup>23</sup>
<b>510(K)Number</b>	<a href="#">K162567</a> <sup>24</sup>
<b>Product Classification</b>	Orthopedic stereotaxic instrument <sup>25</sup> - <b>Product Code</b> OLO <sup>26</sup>
<b>Product</b>	Exactech GPS Total Shoulder Application 3.2mm Vix Bit Orthopedic surgical tool
<b>Code Information</b>	Catalog No. 531-15-08, Lot No. 75296003, 80129003, 81327001
<b>Recalling Firm/ Manufacturer</b>	Exactech, Inc. 2320 NW 66th Ct Gainesville FL 32653-1630
<b>For Additional Information Contact</b>	Kaya Davis 800-392-2832
<b>Manufacturer Reason for Recall</b>	Vix Bit may fracture during use.
<b>FDA Determined Cause</b> <sup>2</sup>	Nonconforming Material/Component
<b>Action</b>	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.
<b>Quantity in Commerce</b>	41 devices
<b>Distribution</b>	Worldwide Distribution: US states of Florida and California, Australia, France, Spain, and United Kingdom.
<b>Total Product Life Cycle</b>	<a href="#">TPLC Device Report</a> <sup>27</sup>

<sup>1</sup> 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](#)<sup>28</sup>.

<sup>2</sup> Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

<sup>3</sup> 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<sup>29</sup>