FDA

Class 2 Device Recall SmartTools Knee System

See Related Information[22]

Date Initiated by Firm	February 20, 2017
Create Date	April 19, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1868-2017
Recall Event ID	76508[23]
510(K)Number	K122326[24]
Product Classification	Orthopedic stereotaxic instrument[25] - **Product Code** OLO[26]
Product	SmartTools Knee System Orthopedic Stereotaxic Instrument
Code Information	Lots:, 130542A1, 1405941, 140146, 140146-1, 140147, 140407A, 140407A-1, 140407B, 140407-B-1, 140860, 140860-1, 141035, 150120, B150120, B150711.
Recalling Firm/ Manufacturer	Orthosoft, Inc. dba Zimmer CAS 75 Queen St #3300 Montreal Canada
For Additional Information Contact	Customer Service 574-371-3071
Manufacturer Reason for Recall	There has been an increase in the number of complaints regarding bent or broken Drive Pins of the Validation Tool manufactured with drawing Revision M to P
FDA Determined Cause [2]	Other
Action	Zimmer Biomet sent an Urgent Medical Device Recall - Lot Removal letter dated February 20, 2017, sent to the affected distributors and hospital Risk Managers and Surgeons via courier. The recall notification included a description of the reason for the recall, affected product, consignee responsibilities, and instructions for responding to the formal recall notification. Distributor responsibilities include: This letter is initiating Phase I of the lot specific field removal of the iASSIST Validation Tool field removal. You are receiving this letter because our records indicate that you have received an affected product that needs to be corrected. Zimmer Biomet is currently making preparations for replacement activities to follow. This document is provided to alert all users of the potential issue and to highlight proper usage of the instrument per the existing surgical techniques in order to minimize the chance of any failure pending a replacement. A separate field removal notification will be issued with detailed instructions in April 2017. You will be notified when a replacement is available. Do not return any product at this time as a part of this field action. Your Responsibilities 1. Review this notification and ensure affected team members are aware of the contents. 2. The affected products can continue to be used until replacements are available. To minimize the chances of bending or breakage during use, please follow the iASSIST Knee Surgical Technique (Ref. 97-9001-101-00 Rev 9) and/or iASSIST Knee Surgical Technique (2-Pod Version) (Ref. 97-9001-004-00 Rev 2), specifically the following warning on pages 36 and 37, respectively. 3. Inspect affected devices before and immediately after use to confirm that the Drive Pins are not bent or broken. In case of breakage, the Drive Pin head will disassemble, as shown below. In the unlikely case of a

	breakage, make sure that both parts are retrieved from the wound. 4. Please keep Zimmer Biomet
Quantity in Commerce	84
Distribution	Nationwide Distribution
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 = ZIMMER[29]

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=76508
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25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=OLO
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28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
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