FDA

Class 2 Device Recall Navitrack System OS Knee Universal

See Related Information[22]

Date Initiated by Firm	October 06, 2011
Create Date	April 26, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1881-2017
Recall Event ID	75614[23]
510(K)Number	K110054[24]
Product Classification	Orthopedic stereotaxic instrument[25] - **Product Code** OLO[26]
Product	Navitrack System - OS Knee Universal, Orthopedic Stereotaxic Instrument CAS Software application intended to assist in the placement of total knee replacement components
Code Information	Part Name: OS Knee Universal, Part Number: ORTHOsoft-UniTkr-2, Affected Lot: ORTHOsoft-UniTkr-2.3.2.6
Recalling Firm/ Manufacturer	Orthosoft, Inc. dba Zimmer CAS 75 Queen St #3300 Montreal Canada
For Additional Information Contact	Kevin Escapule 574-372-4487
Manufacturer Reason for Recall	Zimmer CAS voluntarily conducted a retrospective recall of the Navitrack System - OS Knee Universal software ORTHOsoft-UniTkr-2.3.2.6, due to a calibration sequence crash.
FDA Determined Cause [2]	Software design
Action	Zimmer sent a Medical Device Field Notification letter dated December 6, 2011, to all affected customers. This is a retrospective report of a correction taken on 6 December 2011. The software issues were fixed in the new software version 2.3.3.0. Recall notices were distributed on December 6, 2011. Telephone: 18663367846 (US & Canada) or 5143958883 (International), Email: cassupport@zimmercas.com Customers with questions should call 1-866-336-7846 (US & Canada) 514-395-8883 (International). For questions regarding this recall call 574-372-4487.
Quantity in Commerce	105
Distribution	Worldwide Distribution - US including AZ CA CO FL GA IL IN KS MD MI MN MS OH OR PA SC SD TX VA WA and WI Internationally to Canada, Australia Austria Colombia Denmark France Germany Korea New Zealand Russia South Africa and Thailand
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].