Class 2 Recall Tibial Alignment Guide See Related Information[23]

Date Posted	June 02, 2015
Recall Status[1]	Open
Recall Number	Z-1701-2015
Recall Event ID	71202[24]
Premarket Notification 510(K) Number	K122326[25]
Product Classification	Orthopedic Stereotaxic Instrument[26] - **Product Code** OLO[27]
Product	Tibial Alignment Guide; Orthopedic Stereotaxic Instrument;
Code Information	Item Number: 20-8011-013-00; Lot Numbers: 120265; 110623; 120659; 120794;120659-1; 130134; 120793; 130135
Recalling Firm/ Manufacturer	Zimmer CAS 75 Queen St #3300 Montreal
Manufacturer Reason for Recall	Zimmer CAS has determined that the potential exists for the spikes on the iASSIST Tibial Alignment Guide to bend or break during insertion or extraction from the tibia during use.
FDA Determined Cause [2]	DESIGN: Device Design
Action	Zimmer distributed notices via certified mail on May 14, 2015. Zimmer is removing affected Tibial Alignment Guide iAssist Knee System product from distribution in a two-phased process. Based upon complaint investigation, Zimmer CAS has determined that the potential exists for the spikes on the iASSIST Tibial Alignment Guide to bend or break during insertion or extraction from the tibia during use. Customerswere asked to review the notifictaion, follow the iASSIST Surgical Knee Technique provided, further distribute the notice for any distributed product, inspect devices in use before and after procedures, report any adverse events, and complete the certificate of acknowledgment and return it to CorporateQuality.PostMarket@zimmer.com. Customers with questions concerning this notice, please contact Customer Service at the following address/phone number. Customer Service / Zimmer CAS 75 Queen Street, Suite 3300 Montreal, Quebec, Canada H3C 2N6 Email : cas-support@zimmercas.com, Telephone : 1-514-395-8883, toll free for North America 1-866-336-7846, Fax : 1-866-978-3801. For questions regarding this recall 574-372-4487.
Quantity in Commerce	78 devices
Distribution	Nationwide Distribution including AL, AZ, CA, CA, CO, FL, IN, MI, NJ, NY, OH, OR, PA, TX, VA, and WI.
Total Product Life Cycle	TPLC Device Report[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.