Class 2 Device Recall Stryker Orthopaedics

See Related Information[22]

Date Initiated by Firm	December 02, 2016
Create Date	January 12, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1020-2017
Recall Event ID	75889[23]
Product Classification	Orthopedic manual surgical instrument[24] - **Product Code** LXH[25]
Product	Reunion TSA Peg Alignment Sound Catalog #5901-1038 The Peg Alignment Sound (PIN 5901-1038, Revision A) is an instrument used in the ReUnion TSA shoulder system for confirming seating height and peg alignment of the TSA Self-Pressurizing Polyethylene Glenoid implant prior to final implantation into the glenoid vault. Its purpose is to provide assurance that the drilled holes for seating of the Glenoid implant have been properly prepared using the provided instrumentation
Code Information	Catalog #5901-1038
Recalling Firm/ Manufacturer	Stryker Howmedica Osteonics Corp. 325 Corporate Dr Mahwah NJ 07430-2006
For Additional Information Contact	Mr. Michael Van Ryn 201-831-5000
Manufacturer Reason for Recall	Reunion TSA Peg Alignment Sound broke during surgery.
FDA Determined Cause [2]	Device Design
Action	Stryker Orthopaedics sent an Urgent Medical Device Recall Notification letter dated December 2, 2016, to all affected customers. The letter identified the product, the problem, and the action to be taken by the customer. Customers were asked to inform users of the Urgent Medical Device Recall and forward the notice to all those individuals who need to be aware within their organization. Return all affected products available to: Stryker Orthopaedics/PFA Product Returns Attn: Distribution Inventory Team 325 Corporate Drive Dock M-East Mahwah, NJ 07431 1360184/RA2016-112 Complete and sign the enclosed Business Reply Form and fax a copy to 855-261-3635 or email to SO_M_PRODUCT_FIELD_ACTION_RESPONSE@stryker.com. Customers with questions were instructed to call 201-831-6693.
Quantity in Commerce	131 units
Distribution	Nationwide Distribution
Total Product Life Cycle	TPLC Device Report[26]