Class 2 Device Recall RSP Impaction Fixture

Date Initiated by Firm: February 06, 2017
Create Date: March 08, 2017
Recall Status: Open, Classified
Recall Number: Z-1413-2017
Recall Event ID: 7645623
Product Classification: Impactor24, Product Code HWA25
Product: RSP Impaction Fixture
Code Information: 109931L01, 109931L02, 115670L15, 115670L16, 128092L08, 128092L09, 137917L16, 167828L06, 52258L01, 52258L01A, 87428L01, 76386L01, 76386L02, 81722L01, 81722L02
Recalling Firm/Manufacturer: Encore Medical, LP
9800 Metric Blvd
Austin, TX 78758-5445
For Additional Information Contact: Desiree Wells
512-332-9500
Manufacturer Reason for Recall: During the Turon assembly, the impaction forces caused the polymer, black acetal copolymer from the Impaction Fixture to wear off on the lateral surface of the Humeral Stem titanium plasma spray coating.
FDA Determined Cause: Device Design
Action: There are two field safety notices, one for Consignees who have surgeons that use the impaction fixtures (Version 1) and one for Consignees who had previously indicated their surgeons do NOT use the impaction fixtures (Version 2). The two recall notification letters were sent out on 2/9/17.
Quantity in Commerce: 626 units
Distribution: US, South Korea, Australia, Canada, United Kingdom/Ireland, Germany
Total Product Life Cycle: TPLC Device Report

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.
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.

Links on this page:
http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=153337
3/20/2017