FDA

Class 2 Device Recall RSP Impaction Fixture

See Related Information[22]

Date Initiated by Firm	February 09, 2017
Create Date	March 08, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-1413-2017
Recall Event ID	76456[23]
Product Classification	Impactor[24] - **Product Code** HWA[25]
Product	RSP Impaction Fixture
Code Information	*109931L01, 109931L02, 115670L15, 115670L16, 128092L08, 128092L09, 137917L16, 167829L06, 52258L01, 52258L01A, 67428L01, 76386L01, 76386L02, 81722L01, 81722L02*
Recalling Firm/ Manufacturer	Encore Medical, Lp 9800 Metric Blvd Austin TX 78758-5445
For Additional *Information* Contact	Desiree Wells 512-832-9500
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 [2]	Device Design
Action	There are two field safety notices, one for Consignees who have surgeons that use the impaction fixtures (Verson 1) and one for Consignees who had previously indicated their surgeons do NOT use the impaction fixtures (Verson 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[26]

[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[27].

[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.

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