Class 2 Recall Cochlear Nucleus Sterile Silicone Template

See Related Information[23]

Date Posted	July 20, 2015
Recall Status[1]	Terminated on August 05, 2015
Recall Number	Z-2155-2015
Recall Event ID	71509[24]
Premarket Approval PMA Number	P970051[25]
Product Classification	Implant, Cochlear[26] - **Product Code** MCM[27]
Product	Cochlear Nucleus Sterile Silicone Template Product Usage: The Cochlear Nucleus Sterile Silicone Template is used in the sterile field to check the size of the periosteal pocket, the shape and depth of the implant well and appropriate positions for tie down holes
Code Information	Lot numbers: COH471122 Expiration 5/6/15 and Lot COH471123 Expiration 4/24/15
Recalling Firm/ Manufacturer	Cochlear Americas Inc. 13059 E Peakview Ave Centennial, Colorado 80111-6511
For Additional Information Contact	Tom Pavlik 303-264-2367
Manufacturer Reason for Recall	Cochlear Americas is recalling Nucleus Sterile Silicone Template CI24RE/CI422 part number Z421736 because expired product was distributed.
FDA Determined Cause [2]	PRODUCTION CONTROLS: Process Control
Action	Cochlear sent an Urgent Medical Device Recall letter dated June 5, 2015 via Fed-Ex shipment. The letter identified the affected product, problem and actions to be taken. Customers were instructed to return affected products for replacement.
Quantity in Commerce	26
Distribution	US Nationwide Distribution to CO, OH, OR, MI, and CA.
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.

PMA Database	PMAs with Product Code = MCM and Applicant = COCHLEAR AMERICAS[30] PMAs with Product Code = MCM and Applicant = COCHLEAR CORP.[31]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain