Class 2 Device Recall Opteform Allograft Disc

See Related Information[22]

Class 2 Device Recall Opteform Allograft Disc

Date Initiated by Firm	April 26, 2019
Create Date	May 29, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1688-2019
Recall Event ID	82759[23]
510(K)Number	K043421[24]
Product Classification	Filler, bone void, calcium compound[25] - **Product Code** MQV[26]
Product	Opteform Allograft Disc, 30mm 3mm, 2cc, Catalog Number 600-03-30
Code Information	UDI 10885862093202 Serial Numbers: T31634510, T31788559
Recalling Firm/ Manufacturer	Exactech, Inc. 2320 NW 66th Ct Gainesville FL 32653-1630
Manufacturer Reason for Recall	The Opteform Disc-30mm, Opteform Disc-45mm, and Opteform Disc-90mm were potentially exposed to higher temperatures than those documented in the IFU due to a failure of the cold storage equipment.
FDA Determined Cause [2]	Environmental control
Action	The firm initiated the recall on 04/26/2019 by electronic mail. The notice requested the consignee cease distribution of the product, notify their customers (the user), quarantine all units subject to recall in inventory, and if any units were implanted to follow-up on the patient's condition 30 days after surgery.
Quantity in Commerce	2 units
Distribution	OK, VA, FL
Total Product Life Cycle	

TPLC Device Report[27]

[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[28].

[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.

510(K) Database 510(K)s with Product Code = MQV and Original Applicant = REGENERATION TECHNOLOGIES, INC.[29]

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=82759
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28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=MQV&knumber=&applicant=REGENERATION%20TECHNOLOGIES%2C%20INC%2E

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22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
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