FDA

Class 2 Device Recall OviTex Reinforced BioScaffold 20x20cm

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Back to Search Results

Class 2 Device Recall OviTex Reinforced BioScaffold 20x20cm

See Related Information [22]

Date Initiated by Firm	April 06, 2018
Create Date	November 09, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0420-2019
Recall Event ID	81166[23]
510(K)Number	K153633[24]
Product Classification	Mesh, surgical[25] - **Product Code** FTM[26]
Product	OviTex Reinforced BioScaffold 20x20cm, Part Number F10254-2020G
Code Information	ERT-6H13
Recalling Firm/ Manufacturer	AROA Biosurgery, LTD. 69 Gracefield Road Lower Hutt New Zealand
Manufacturer Reason for Recall	Degradation of the PGA suture material used in the manufacture of the resorbable mesh devices was observed during an on-going product stability study. Further investigation indicated that devices over 18-months showed evidence of no longer meeting the pre-defined ball burst specification respective to the number of tissue layers.
FDA Determined Cause [2]	Other
Action	Beginning in April 2018, customers were visited by representatives and the affected units were replaced.
Quantity in Commerce	881 total
Distribution	The products were distributed to the following US states: AL, CA, FL, IN, MA, MI, NH, and NY.
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 = FTM and Original Applicant = Aroa Biosurgery Limited