**Class 2 Device Recall OviTex Reinforced BioScaffold 20x20cm**

**Date Initiated by Firm**
April 06, 2018

**Create Date**
November 09, 2018

**Recall Status**
Open, Classified

**Recall Number**
Z-0420-2019

**Recall Event ID**
81186

**510(K)Number**
K153633

**Product Classification**
Mesh, surgical - Product Code FTM

**Product**
OviTex Reinforced BioScaffold 20x20cm, Part Number F10254.2020G

**Recalling Firm/Manufacturer**
AROA Biosurgery, LTD.
89 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 relative to the number of tissue layers.

**FDA Determined Cause**
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

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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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=167628).

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

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https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=167628

11/19/2018