FDA

Class 2 Device Recall Endoform Dermal Template

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See Related Information[22]

Date Initiated by Firm	September 18, 2018
Create Date	November 02, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0378-2019
Recall Event ID	81161[23]
510(K)Number	K171231[24]
Product Classification	Dressing, wound, collagen[25] - **Product Code** KGN[26]
Product	Endoform Dermal Template 2x2, SKU 529312 Product Usage: Endoform Dermal Template is a sterile, single use ovine forestomach derived extracellular matrix intended to cover, protect and provide a moist wound environment.
Code Information	Lot numbers: EDT-7I01 EDT-7K01 EDT-7L05
Recalling Firm/ Manufacturer	Aroa Biosurgery 2 Kingsford Place Otara Auckland New Zealand
For Additional Information Contact	Kevin Sisk 860-3377730
Manufacturer Reason for Recall	Potential for pouch seal failure
FDA Determined Cause [2]	Employee error
Action	The firm sent a Customer Notification letter dated September 2018. The letter identified the affected product, problem and actions to be taken. Customers are encouraged to visually inspect the seals on devices from these lots prior to use with particlar care. Should you observe a comprimised seal, please discard the device and select a new, fully sealed device for use.
Quantity in Commerce	8,853 total boxes
Distribution	US Nationwide Distribution
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.