FDA

Class 2 Device Recall First Aid Sterile Gauze Pad

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See Related Information[22]

Date Initiated by Firm	October 16, 2018
Create Date	November 30, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-0525-2019
Recall Event ID	81555[23]
Product Classification	Gauze / sponge,nonresorbable for external use[24] - **Product Code** NAB[25]
Product	Family Wellness First Aid Sterile Gauze Pad 3 in x 3 in, 10 CT. White, bleached, non-woven, rayon/polyester sterile Gauze Pad 3 inch x 3 inch, 12-ply 10 count cardboard box
Code Information	ASO Item No. 780655, Batch/Lot # 2384-20180524
Recalling Firm/ Manufacturer	ASO, LLC 300 Sarasota Center Blvd Sarasota FL 34240-9381
For Additional Information Contact	Steve Walter 941-378-6649
Manufacturer Reason for Recall	Potential that gauze pads may not be fully sterilized
FDA Determined Cause [2]	Under Investigation by firm
Action	ASO, LLC notified customers of the recall on about 10/16/2018 via "URGENT: MEDICAL DEVICE RECALL" letter sent to corporate. Instructions were to immediately stop using/distributing the affected gauze pads, place them in quarantine, and return to ASO LLC. Customers were also instructed to complete and return the response form.
Quantity in Commerce	218 cases (72, 10-ct boxes per case)
Distribution	Distributed nationwide to AR, FL, IA, IN, KY, NY, OK, TX, UT, VA.
Total Product Life Cycle	TPLC Device Report[26]

[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[27].