Class 2 Device Recall First Aid Sterile Gauze Pad

Date Initiated by Firm: October 16, 2018
Create Date: November 30, 2018
Recall Status: Open, Classified
Recall Number: Z-0525-2019
Recall Event ID: 81558
Product Classification: Gauze/sponge nonresorbable for external use - Product Code NAB
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: 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

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.