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Class 2 Device Recall Bivona Tracheostomy Tube Tracheostomy Tubes

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Date Initiated by Firm
April 02, 2018

Create Date
June 07, 2018

Recall Status
Open, Classified

Recall Number
Z-2114-2018

Recall Event ID
80092

Product Classification
Tube, tracheostomy (w/wo connector) - Product Code BTO

Product
Bivona®, Tracheostomy Tube Tracheostomy Tubes

Code Information
Part No. (Lot No.): CMZ3241N (DS009718), ST16N80NSC194N (DS009794), SU15AN70NSC153N (DS009577), FT17IN60NGC114N (DS009894), CMZ3331N (DS009761), UX17GS50NSF046N (DS009609), FT17IN60NGC114N (DS009861), AA16ES70NSC110N (DS009586), FT17IN60NGC111N (DS009856), FT16IN60NGC053N (DS009540), FU15AN55NSA076N (DS009464), AT17IS60NGC105N (DS009811)

Recalling Firm/Manufacturer
Smiths Medical ASD Inc
6000 Nathan Ln N
Minneapolis MN 55442-1690

For Additional Information Contact
763-383-3072

Manufacturer Reason for Recall
Carton labeling is printed with "Sterile" indicated labeling, however the device is not sold as sterile.

FDA Determined Cause
Error in labeling

Action
Customers were notified via letter on approximately 04/02/2018. Instructions included to determine if there are any affected Customized Bivona® Tracheostomy Tubes in inventory, notify customers if the devices have been further distributed, arrange for the return of affected devices, and complete and return the acknowledgement response form.

Quantity in Commerce
18 units

Distribution
Domestic distribution to CA, FL, GA, ID, NJ, NM, OH, VA. International distribution to France.

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.

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.

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=164546 6/18/2018