FDA

See Related Information[22]

Class 2 Device Recall Bivona Tracheostomy Tube Tracheostomy Tubes

Date Initiated by Firm	April 02, 2018
Create Date	June 07, 2018
Recall Status[1]	Open[3], Classified
Recall Number	Z-2114-2018
Recall Event ID	80092[23]
Product Classification	Tube, tracheostomy (w/wo connector)[24] - **Product Code** BTO[25]
Product	Bivona¿ Tracheostomy Tube Tracheostomy Tubes
Code Information	Part No. (Lot No.): CMZ3241N (DS009716), ST16EN80NSC194N (DS009794), SU15AN70NSC153N (DS009577), FT17IN60NGC114N (DS009894), CMZ3331N (DS009761), XU17GS50NSF046N (DS009609), FT17IN60NGC114N (DS009861), AA16ES70NSC110N (DS009586), FT17IN70NSC111N (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 [2]	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	*16 units*
Distribution	Domestic distribution to CA, FL, GA, ID, NJ, NM, OH, VA. International distribution to France.
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].

[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.