Class 2 Device Recall RUSCH

See Related Information 22

Date Initiated by Firm	November 22, 2016
Create Date	December 16, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0771-2017
Recall Event ID	75781[23]
510(K)Number	K010420[24]
Product Classification	Catheter, urological[25] - **Product Code** KOD[26]
Product	RUSCH, Pocket PAC IC Intermittent Cath Kit, 8 FR, 12 FR, 14 FR, 10 FR and 16 FR, Rx Only, Sterile, Intermittent self-catheterization
Code Information	Product Code: 10096080, Lot number: 74F1501853 (8 FR); Product Code: 10096120, Lot numbers: 74E1602795, 74F1503201, 74G1600723 & 74J1500576 (12 FR); Product Code: 10096140, Lot numbers: 74A1600023, 74A1601105, 74A1602234, 74D1602007, 74E1602235, 74E1602796, 74F1501855, 74G1600486, 74H1500530 & 74L1500363 (14 FR); Product Code: 10096100, Lot numbers: 74A1600799, 74A1600800, 74A1602236, 74A1603122, 74D1600231, 74D1600923, 74D1601540, 74D1602136, 74E1600845, 74E1601768, 74E1602237, 74F1501857, 74F1501962, 74F1601966, 74F1601988, 74H1500534, 74H1500978, 74J1501157, 74K1502306, 74L1500364, 74L1501303, 74L1501938, 74M1500227 and 74M1501087 (10 FR) and Product Code: 10096160, Lot numbers: 74A1600024, 4A1600801, 74A1601106, 74A1603123, 74D1601541, 74E1600846, 74E1602797, 74G1600724, 74H1500979, 74J1501158, 74K1501837, 74L1501202 &74L1501939 (16 FR)..
Recalling Firm/ Manufacturer	Teleflex Medical 2917 Weck Dr Research Triangle Park NC 27709-0186
For Additional Information Contact	Alice Harper 610-378-0131
Manufacturer Reason for Recall	Labeling Inconsistency: The products have been labeled with the incorrect expiration date which exceeds the actual, validated 35-month shelf life.
FDA Determined Cause [2]	Error in labeling
Action	Teleflex sent an Urgent Medical Device Recall Notification letter dated November 22, 2016, to all affected consignees. The letter identified the product, the problem, and the action to be taken by the customer. Customers with affected stock, immediately discontinue use and quarantine any affected products. To return product, customers were advised to complete the enclosed Recall Acknowledgment Form and fax it to 1-855-419-8507, Attn: Customer Service or email to recall@teleflex.com. Customers with no affected stock should also complete the enclosed Recall Acknowledgment Form to confirm receipt of the letter. Customers with questions should contact Customer Service at 1-866-246-6990.
Quantity in Commerce	102,843 units