Class 1 Device Recall Hudson RCI Sheridan Preformed

Date Initiated by Firm: May 24, 2019
Create Date: June 19, 2019
Recall Status: Open, Classified
Recall Number: Z-1762-2019
Recall Event ID: 82964
510(K) Number: K822082
Product Classification: Tube, tracheal (w/wo connector)
Product: Hudson RCI Sheridan:
1) Preformed 6.0 mm, Product Codes: a) 5-22212, b) 5-22312, c) 5-22112, d) 5-22012,
2) Preformed 6.5 mm, Product Codes: a) 5-22313, b) 5-22213, c) 5-22013, d) 5-22113,
3) Preformed 7.0 mm, Product Codes: a) 5-22214, b) 5-22114, c) 5-22014, d) 5-22114,
4) Preformed 7.5 mm, Product Codes: a) 5-22215, b) 5-22315,
5) Preformed 8.0 mm, Product Codes: a) 5-22216, b) 5-22316,
6) Preformed 8.5 mm, Product Codes: 5-22217
Product Usage: Tracheal tube/airway management
Code Information: Hudson RCI Sheridan: 1) Preformed 6.0 mm, Product Codes: a) 5-22212, Lot Numbers: 73J1600378 73K1600730 73L1600665 73M1600158 73B1700049 73B1700313 73C1700416 73D1700643 73F1700034 73F1700171 73F170073 Numbers: 73K1600151 73L1600593 73M1600384 73K1600732 73L1600668 73M1600160 73A1700116 73A1700738 73C1700698 73D1700647 73E1700760 73F170041 Numbers: 73K1600149 73L1600667 73A1700114 73B1700314 73C1700694 73D1700644 73E1700400 73G1700067 73H1700648 73J1700138 73J170048 Numbers: 73J1600384 73L1600164 73L1600688 73M1600161 73A1700117 73A1700739 73C1700566 73D1700648 73F1700656 73F1700731 73G17 Numbers: 73F1700027 73J1700427 73F1800342 73K1800162 73K1800730 73L1700134 73M1700494 73P1700729 73G170010 73H1700617 73J1700138 73J170044 Numbers: 73J1600384 73L1600869 73M1600162 73C1700417 73D1700134 73D1700649 73F1700174 73F1700732 73H1700344 73H1700789 73J170041

Recalling Firm/ Manufacturer: Teleflex Medical
3015 Carrington Mill Blvd
Morrisville NC 27560-5437

Manufacturer Reason for Recall: This voluntary recall is due to reported complaints (<0.0025% of all in scope distributed product) indicating that there is an increased incidence of specific lot numbers.

FDA Determined Cause 2: Under Investigation by firm

Action: Teleflex sent an Urgent Medical Device Recall letter dated May 24, 2019 to customers. The letter identified the affected product, problem and actions to be taken. Distributors were directed to notify their customers and request the customer return the recalled products to them for consolidation and subsequent return to Teleflex Medical.

For questions contact your local sales representative or Customer Service at 1-866-396-2111

Quantity in Commerce: 186592 units

Distribution: Worldwide - US Nationwide Distribution

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

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.

510(K) Database: 510(K)s with Product Code = BTR and Original Applicant = SHERIDAN CATHETER CORP.