Class 1 Device Recall Hudson RCI Sheridan Preformed

Date Initiated by Firm	May 24, 2019
Create Date	June 19, 2019
Recall Status[1]	Open[3], Classified
Recall Number	Z-1762-2019
Recall Event ID	82964[23]
510(K)Number	K822082[24]
Product Classification	Tube, tracheal (w/wo connector)[25] - **Product Code** BTR[26]
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) 5-22314, 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 73F170072 Numbers: 73K1600151 73L1600512 73M1600159 73A1700737 73B1700423 73C1700697 73D1700426 73E1700561 73E1700721 73F1700173 73F17007 5-22112, Lot Numbers: 73L1600359 73M1600155 73A1700278 73C1700415 73F1700168 73G1700426 73H1700615 73L1700650 73B1800492 73H18006 Numbers: 73J1600382 73K1600384 73K1600732 73L1600668 73M1600160 73A1700116 73A1700738 73C1700698 73D1700647 73E1700760 73F17004 Numbers: 73K1600149 73L1600666 73A1700114 73B1700314 73C1700694 73D1700644 73F1700400 73G1700428 73H1700342 73H1700788 73J17004 7.0 mm, Product Codes: a) 5-22214, Lot Numbers: 73J1600379 73K1600593 73L1600667 73B1700315 73C1700695 73D1700425 73E1700493 73G1700 Lot Numbers: 73J1600383 73L1600164 73L1600868 73M1600161 73A1700117 73A1700739 73C1700566 73D1700648 73F1700065 73F1700731 73G17 Numbers: 73F1700027 73K1700427 73F1800342 73K1800182 73K1800730 d) 5-22114, Lot Numbers: 73F1700399 73K1800734 4) Preformed 7.5 mm, F Numbers: 73J1600380 73K1600150 73C1700257 73C1700565 73D1700645 73E1700494 73F1700729 73G1700610 73H1700617 73J1700138 73J17004 Numbers: 73J1600384 73L1600869 73M1600162 73C1700417 73D1700134 73D1700649 73F1700174 73F1700732 73H1700344 73H1700789 73J17004

	Numbers: 73J1600381 73K1600383 73L1600162 73L1600511 73A1700115 73A1700736 73B1700422 73C1700258 73C1700696 73D1700646 73E170049 5-22316, Lot Numbers: 73C1700260 73C1700795 73F1700402 73H1700345 73H1700790 73L1700517 73B1800501 73D1800477 73F1800353 73G18008 Numbers: 73L1600163 73L1600363 73C1700796 73F1700555 73H1700343 73J1700140 73L1700515 73M1700148 73A1800025 73A1800303 73B18003
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 lo
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 t Distributors were directed to notify their customers and request the customer return the recalled products to them for consolidation and subsequent return to 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[27]

[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.[29]

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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm

21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=82964
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K822082
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=BTR
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=BTR
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=BTR
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
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20. /scripts/cdrh/cfdocs/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=82964
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K822082
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27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=BTR
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=BTR&knumber=&applicant=SHERIDAN%20CATHETER%20CORP%2E