FDA

Class 2 Device Recall CADD(R) Medication Cassette with clamp and female Luer

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Class 2 Device Recall CADD(R) Medication Cassette with clamp and female Luer

Date Initiated by Firm	June 05, 2017
Create Date	August 25, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-3071-2017
Recall Event ID	77555[23]
510(K)Number	K843772[24]
Product Classification	Pump, infusion[25] - **Product Code** FRN[26]
Product	CADD(R) Medication Cassette Reservoir with clamp and female Luer. Non vented stopper included, REF 21-7002-24, Rx only, STERILE EO, Manufacturer Smiths Medical ASD, Inc.
Code Information	lot number 16X659
Recalling Firm/ Manufacturer	Smiths Medical ASD Inc. 6000 Nathan Ln N Minneapolis MN 55442-1690
Manufacturer Reason for Recall	The medication cassette reservoir, part number 21-7002-24, with lot number 16X659, may have been manufactured with the incorrect pressure plate and the tubing used on the cassette may have been routed incorrectly.
FDA Determined Cause [2]	Process change control
Action	Consignees (may include distributors and hospitals) in Japan were notified the week of June 5, 2017. Recall letters were delivered by Smiths Medical, Japan sales representatives during the week of 06/19/2017. The consignees were directed to return any affected devices in their possession and receive replacements. Their Smiths Medical sales representative will collect the affected product and replacement product will be sent to them.
Quantity in Commerce	17280 units
Distribution	Japan, China, US
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 it is updated for a final time when the recall is terminated. Learn more about medical device recalls[28].
[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 = FRN and Original Applicant = DELTEC SYSTEMS, INC.[29]