FDA

Class 2 Device Recall Alaris Pump Module model 8100

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See Related Information[22]

Date Initiated by Firm	June 12, 2017
Date Posted	June 19, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-2700-2017
Recall Event ID	77279[23]
510(K)Number	K950419[24]
Product Classification	Pump, infusion[25] - **Product Code** FRN[26]
Product	Alaris Pump Module model 8100
Code Information	Notification will be distributed to all Alaris Pumps customers with pumps manufactured between June 2002 through June 2004.
Recalling Firm/ Manufacturer	CareFusion 303, Inc. 10020 Pacific Mesa Blvd San Diego CA 92121-4386
For Additional Information Contact	Michelle Dadal 858-617-5925
Manufacturer Reason for Recall	There is a potential risk that could cause unintended flow in the older, centered sear door latch design in the Alaris Pump module model 8100.
FDA Determined Cause [2]	Device Design
Action	An Urgent Medical Device Recall letter will be sent on 6/12/17 to customers to inform them that BD is issuing this letter to inform you of a potential risk associated with the Alaris Pump module. Firm identified a specific scenario that could cause unintended flow in the older, centered sear door latch design in the Alaris Pump module model 8100. This scenario is reproducible under the following situations: a) the user does not close the roller clamp on the IV administration set before the pump door is opened as recommended, and b) opening the pump door using an atypical technique with the door latch with the centered sear design. The letter instructs customers If their device has a centered-sear that was manufactured between June 2002 to June 2004, clearly mark and sequester (e.g. Biomed department) the Alaris Pump module that exhibited the issue. Notify CareFusion Customer Advocacy at 888-812-3266 or customerfeedback@carefusion.com to coordinate an onsite remediation or send the devices to the BD Service Depot.
Quantity in Commerce	35,940 units .
Distribution	US and Canada
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.