

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Alaris Pump Module model 8100
6 510(k)|DeNovo8| Registration & | Adverse | Recalls11

|Recalls¹¹|PMA¹²|HDE¹³|Classification¹⁴|Standards¹⁵

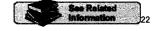
Events¹⁰ Listing⁹

CFR Title 21¹⁶[Radiation-Emitting Products¹⁷|X-Ray Assembler¹⁸|Medsun Reports¹⁹|CLIA²⁰|TPLC²¹

New Search

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Class 2 Device Recall Alaris Pump Module model 8100



Date Initiated by Firm

August 09, 2017

Create Date

October 19, 2017

Recall Status¹

Open³, Classified

Recall Number

Z-0026-2018

Recall Event ID

7798723

510(K)Number

K950419²⁴

Product Classification

Pump, infusion²⁵ - Product Code FRN²⁶

Product

Alaris Pump Module model 8100 manufactured between November 2011 and

March 2012;

Alaris Pump Module serviced with LVP Mechanism Sub Assembly (P/N) 10942012

between November 2011 and March 2012;

Alaris Pump module Bezel Kit Assembly (P/N) 10964559) shipped between

November 2011 and March 2012.

The Alaris Pump module is a large volume infusion pump offered under the Alaris System. The Alaris Pump module will deliver medication and fluids using the IV administration sets for continuous or intermittent delivery through clinically acceptable routes of administration such as intravenous or epidural.

Code Information

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Recalling Firm/ Manufacturer

CareFusion 303, Inc. 10020 Pacific Mesa Blvd San Diego CA 92121-4386

For Additional Information Contact

BD Support Center 888-562-6018

Manufacturer Reason for Recall

The recalling firm has received reports of increased or decreased flows that have occurred in certain pumps.

FDA Determined Cause ²

Unknown/Undetermined by firm

Action

BD sent an Urgent: Medical Device Recall Notification dated September 1, 2017. The customer letter will instruct the customers to remove the pump from service if it shows signs of infusion at an unexpected rate and not to use the affected devices in high risk areas if possible. The customer notification letter will be addressed to the Directors of Nursing, Risk Management, and Biomedical Engineering. Customers will be required to confirm receipt of the notification by returning the Recall Response Card to BD by postage-paid, self-addressed mail, fax, or email. For further questions, please call (888) 562-6018.

Quantity in Commerce

31,622 units (28,224 in US)

Distribution

Worldwide Distribution - USA (nationwide) and to the countries of : Canada, Australia, UAE,

Kuwait, Saudi Arabia, South Africa

Total Product Life Cycle

TPLC Device Report²⁷

510(K) Database

510(K)s with Product Code = FRN and Original Applicant = IMED CORP.²⁹

Links on this page:

- 1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
- 2. http://www.addthis.com/bookmark.php

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 recalls²⁸.

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.