Class 2 Device Recall Alaris Pump Module model 8100

Date Initiated by Firm: August 09, 2017
Create Date: October 19, 2017
Recall Status: Open, Classified
Recall Number: Z-0026-2018
Recall Event ID: 77987
510(K) Number: K950419
Product Classification: Pump, infusion - Product Code FRN
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:
50, 13617352, 13617353, 13617357, 13617368, 13617370, 13617372, 13617373, 13617374, 13617377, 13617378, 13617380, 13617391, 13617394, 13617399, 13617403, 13617404, 13617405, 13617406, 13617407, 13617408, 13617409, 13617413, 13617415, 13617425, 13617428, 13617430, 13617435, 13617436, 13617438, 13617439, 13617440, 13617441, 13617448, 13617454, 13617456, 13617457, 13617459, 13617461, 13617468, 13617469, 13617473, 13617476, 13617483, 13617492, 13617493, 13617495, 13617496, 13617497, 13617502, 13617506, 13617507, 13617508, 13617509, 13617510, 13617511, 13617518, 13617519, 13617526, 13617529, 13617530, 13617533, 13617534, 13617535, 13617538, 13617539, 13617540, 13617546, 13617556, 13617565, 13617566, 13617581, 13617586, 13617587, 13617588, 13617589, 13617590, 13617591, 13617593, 13617594, 13617596, 13617599, 13617601, 13617604, 13617607, 13617613, 13617614, 13617621, 13617622, 13617623, 13617624, 13617626, 13617627, 13617634, 13617635, 13617636, 13617637, 13617638, 13617639, 13617641, 13617642, 13617643, 13617644, 13617645, 13617654, 13617668, 13617674, 13617686, 13617687, 13617689, 13617690, 13617691, 13617694, 13617695, 13617696, 13617698, 13617699, 13617709, 13617710, 13617714, 13617718, 13617724, 13617725, 13617740, 13617742, 13617745, 13617747, 13617749, 13617750, 13617762, 13617763, 13617764, 13617766, 13617768, 13617770, 13617777, 13617784, 13617789, 13617790, 13617791, 13617792, 13617793, 13617794, 13617795, 13617796, 13617799, 13617800, 13617801, 13617804, 13617807, 13617810, 13617811, 13617812, 13617813, 13617814, 13617818, 13617819, 13617820, 13617821, 13617822, 13617823, 13617824, 13617826, 13617829, 13617830, 13617831, 13617833, 13617834, 13617836, 13617838, 13617840, 13617841, 13617842, 13617844, 13617845, 13617847, 13617848, 13617849, 13617851, 13617853, 13617854, 13617856, 13617857, 13617858, 13617859, 13617860, 13617861, 13617863, 13617865, 13617867, 13617868, 13617869, 13617871, 13617872, 13617874, 13617875, 13617881, 13617882, 13617883, 13617884, 13617885, 13617890, 13617894, 13617895, 13617897, 13617898, 13617904, 13617912.
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Recalling Firm/Manufacturer
CareFusion 303, Inc.
10020 Pacific Mesa Blvd
San Diego CA 92121-4366

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 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
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