Class 2 Device Recall Alaris Pump Module model 8100

[22]

Date Initiated by Firm	August 09, 2017
Create Date	October 19, 2017
Recall Status[1]	Open[3], Classified
Recall Number	Z-0026-2018
Recall Event ID	77987[23]
510(K)Number	K950419[24]
Product Classification	Pump, infusion[25] - **Product Code** FRN[26]
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, 13617646, 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, 13617767, 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 92121-4386
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 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 = IMED CORP.[29]

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