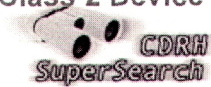




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Class 2 Device Recall CSI, Orbital Atherectomy System (OAS) Saline Infusion Pump

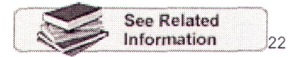


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Class 2 Device Recall CSI, Orbital Atherectomy System (OAS) Saline Infusion Pump



Date Initiated by Firm April 14, 2017

Create Date May 20, 2017

Recall Status¹ Open³, Classified

Recall Number Z-2122-2017

Recall Event ID [76953²³](#)

PMA Number [P130005S002²⁴](#)

Product Classification Catheter, coronary, atherectomy²⁵ - **Product Code MCX²⁶**

Product CSI, Orbital Atherectomy System (OAS) Saline Infusion Pump, Rx only, Part Number: 7-10014, Model Number: SIP-3000.

Code Information Lot Number, 92254, 92693, 106281, 106282, 106283, 106284, 106285, 106286, 106287, 106288, 106290, 106543, 118121, 118223, 121782, 123165, 123489, 123547, 123808, 123878, 124088, 124289, 124925, 124927, 124989, 125310, 125347, 125362, 126696, 126797, 126925, 127026, 127155, 127221, 127348, 127614, 127742, 127834, 128001, 128027, 128132, 128179, 128326, 129266, 129303, 132418, 132839, 132966, 133231, 133429, 133759, 133880, 134057, 134318, 134534, 134966, 135199, 135372, 135791, 135941, 136729, 136881, 136883, 137221, 137361, 137657, 137862, 138218, 138462, 138614, 139049, 139295, 139621, 140470, 140606, 142474, 142596, 142604, 142909, 143084, 143213, 143277, 143335, 143419, 143553, 143556, 143806, 144066, 144276, 144496, 145536, 145946, 146051, 146199, 146337, 146401, 146518, 146843, 146999, 147508, 147530, 148129, 148169, 148400, 148712, 148897, 149117, 149268, 149527, 150273, 150285, 150774, 150831, 151196, 151228, 151440, 151635, 151867, 151994, 152092, 152178, 152321, 152389, 152522, 152889, 153280, 153678, 154011, 154434, 154682, 154948, 155270, 156044, 156340, 156683, 156713, 157869, 158004, 152178, 152321, 158124, 158234, 158370, 158422, 158558, 158617, 160312, 160352, 160995, 161165, 161241, 161328, 161466, 161603, 161679, 161774, 161892, 162318, 162344, 162384, 162402, 162421, 162439, 163493, 163600, 164048, 164293, 164561, 164873, 165087, 165353, 165811, 165971, 166068, 166226, 166653, 166863, 166907, 167024, 167115, 167146, 168006, 168048, 168052, 168087, 168093, 168143, 168173, 168589, 169662, 170066, 170315, 170350, 170385, 171566, 171679, 171915, 172145, 172379, 172490, 172491, 172755, 172859, 172871, 173226, 173486, 173783, 174051, 174434, 174621, 174637, 174659, 175087, 175167, 176653, 177218, 177359, 177385, 177625, 178212, 178237, 178742, 179133, 179287, 179558, 179602, 179649, 179955, 180225, 180360, 180463, 180629, 181317, 181320, 181556, 181586, 182441, 182442, 182494, 182495, 182537, 182539, 183099, 183101, 183150, 183400, 186393, 186683, 186820, 186881, 187241, 187242, 187398, 101182a, 101534A, 102274a, 103369a, 104183B, 105371a, 106346A, 106346b, 108335A, 110016A, 111785a, 111785b, 114148a, 114964a, 49267-4A, 50805A, 50805a, 50891A, 50949A, 50949B, 51191A, 51344A, 51345A, 51498A, 51498B, 51570A, 51571a, 51725A, 52006A, 52089A, 52090B, 52253A, 52258A, 52258b, 52347A, 52377A, 52378A, 52666a, 52890a, 52907A, 52908a, 52915B, 52915C, 52963A, 52968a, 53675B, 53689A, 53802A, 53802B, 54321A, 54321B, 54321C, 54814A, 54826A, 54827A, 54828A, 54829A, 54996A, 55065B, 55097A, 55097B, 55097C, 55100A, 55133A, 55198A, 55286a, 55507a, 55973A, 56195A, 56195B, 56313A, 56313B, 56417A, 56421A, 56638A, 56638B, 56697A, 56732A, 56733A, 56810A, 56810B, 56811A, 56951A, 56952A, 57095a, 57096A, 57098B, 57215A, 57216A, 57223A, 57238A, 57281A, 57342a, 57407A, 57454A, 57610A, 57691A, 57692a, 57864A, 57866a, 57930A, 57974A, 57992B, 58052A,

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Recalling Firm/ Manufacturer	Cardiovascular Systems Inc 1225 Old Highway 8 NW Saint Paul MN 55112-6416
Manufacturer Reason for Recall	Cardiovascular Systems, Inc. (CSI), has initiated a recall to remove 1,396 7-10014 Saline Infusion Pumps (SIP) which were distributed by CSI between 07 April 2015 and 04 April 2017. The 7-10014 pumps may switch to stand-by during use requiring the pump to be reset prior to continuing treatment. To date, none of the associated complaints have resulted in any patient harm.
FDA Determined Cause ²	Device Design
Action	Consignees were sent on 4/14/2017 a CSI "Urgent Medical Device Recall" letter dated 14 APRIL 2017. The letter listed the Affected Product, Recall Description, SIP Replacement and Return & contact information. Consignees were notified the pumps will be replaced and the process is anticipated to be completed 31 August 2017. Consignees may continue to use their pumps however if a yellow light fault is observed and the troubleshooting per the IFU does not resolve the fault, discontinue use of the pump and notify CSI. Consignees were requested to complete and return the Customer Acknowledgement Form. For further information contact CSI sales Representative of Recall coordinator Jake Mellem at jmellem@csi360.com, 651-259-2819 - Tel.
Quantity in Commerce	1,396
Distribution	US: AK, AL, AR, AZ, CA, CO, CT, DC, DE, FL, GA, HI, IA, ID, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, MT, NC, ND, NE, NH, NJ, NY, OH, OK, OR, PA, RI, SC, TN, TX, UT, VA, WA, WI, AUSTRIA, GERMANY, JAPAN, SWITZERLAND.
Total Product Life Cycle	<u>TPLC Device Report</u> 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.

PMA Database [PMAs with Product Code = MCX and Original Applicant = CARDIOVASCULAR SYSTEMS, INC.](#)²⁹

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