Class 2 Device Recall S5 Control Panel for 2 Mast Roller Pumps 85

Class 2 Device Recall S5 Control Panel for 2 Mast Roller Pumps 85

See Related Information[22]

Date Initiated by Firm	November 12, 2010
Date Posted	January 26, 2011
Recall Status[1]	Terminated [3] on July 13, 2012
Recall Number	Z-0960-2011
Recall Event ID	57609[23]
510(K)Number	K060053[24]
Product Classification	Cardiopulmonary Bypass Heart-Lung Machine Console[25] - **Product Code** DTQ[26]
Product	S5 Control Panel for 2 Mast Roller Pumps 85, Part No.: 28-95-85, Sorin Group Deutschland Gmbh, Lindberghstrasse 25, Munchen, Germany, Sorin Group USA, Inc., 14401 W. 65th Way, Arvada, CO 80004. Used to perform, control and monitor extracorporeal blood circulation during an operation for up to six hours.
Code Information	Serial Numbers: 50E65159 to 50E65165
FEI Number	1718850
Recalling Firm/ Manufacturer	Sorin Group USA, Inc. 14401 W 65th Way Arvada CO 80004
For Additional Information Contact	303-467-6306
Manufacturer Reason for Recall	Touch screen may become unresponsive, inhibiting user input.
FDA Determined Cause [2]	Device Design
Action	All affected US customers and distributors were notified by certified mail on Nov 12, 2010 via a Field Correction letter. They were told that they would be contacted by Sorin to arrange an appointment to inspect and replace affected touch screens on site. They were told that they could safely continue using their S5 systems in accordance with the Operator's Manual and previously supplied instructions until the inspection and necessary replacement had been completed. A customer response form was also included for completion and return to the firm. Customers can contact the firm if they have any questions.
Quantity in Commerce	2 unit
Distribution	Worldwide Distribution.
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] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29].

510(K) Database 510(K)s with Product Code = DTQ[30]

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23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=57609
24. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K060053
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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
29. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=7.55
30. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=DTQ&knumber=&applicant=Sorin%20Group%20Deutschland%20GmbH

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

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21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=57609
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28. https://www.fda.gov/medical-devices/medical-device-recalls/what-medical-device-recall
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