FDA Home > Medical Devices > Databases

Class 2 Device Recall CareFusion

Date Posted: September 23, 2014
Recall Status: Open
Recall Number: Z-2689-2014
Recall Event ID: 689562
Premarket Notification 510(K) Number: K315226
Product: CareFusion AirLife Heated Infant Breathing Circuit

Code Information:
All lots of the following products: 1) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10127-4H1; 2) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10331N-4S2; 3) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10351-4H2; 4) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10287-4S2; 5) CIRCUIT RESP INFANT PV HD 5FT 30CS, Product Code 10392-503; 6) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 10485-4H2; 7) CIRCUIT INFANT INSP LINE HDT 8FT 30CS, Product Code 10520-504; 8) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10555-4S2; 9) CIRCUIT INFANT INSP LINE HDT 5FT 30CS, Product Code 10880-4S2; 10) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10706-4S2; 11) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10790-4S2; 12) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10814-4S2; 13) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10849-4S2; 14) CIRCUIT RESP INFANT 3FT HD 30CS, Product Code 10885-4H2; 15) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 10884-4S2; 16) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 10887-4H2; 17) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 11785-4H2; 18) CIRCUIT RESP INFANT DUAL DISP 30CS, Product Code 1063-4H1; 19) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 10705-4S2; 20) CIRCUIT RESP INFANT 3FT HD HI FI 30CS, Product Code 1998-4H1; 21) INFANT RESP CIRC HD 4FT, Product Code 2119-4S2G; 22) INFANT RESP CIRC HD 4FT, Product Code 2120-4S2G; 23) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 4319-4H2; 24) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 4326-4H2; 25) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 4652-501; 26) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 4677-4H2; 27) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 5665-4H2; 29) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 5682-4H9; 30) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 5732-4H1; 31) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 5866-4H2; 32) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 6002-4H2; 33) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 6004-501; 34) CIRCUIT RESP INFANT PV HD 5FT 30CS, Product Code 6074-4H1; 35) CIRCUIT RESP PED 7FT HD 20CS, Product Code 6274-4H2; 36) CIRCUIT RESP PED 7FT HD 20CS, Product Code 6301-4H2; 37) INFANT RESP CIRC HD 4FT, Product Code 6313-501; 38) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 6459-4H2; 39) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 6485-4H2; 40) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 6583-4H2; 41) WYE KIT INFANT 30CS, Product Code 6603-504; 42) CIRCUIT INFANT 6FT HD INSP LINE 30CS, Product Code 6662-4H2; 43) CIRCUIT RESP INFANT 4FT HD 30CS, Product Code 6921-4H2; 44) CIRCUIT RESP INFANT 5FT HD 30CS, Product Code 6942-4H2; 45) CIRCUIT INFANT 4FT HD 30CS, Product Code 7100-4S2; 46) CIRCUIT RESP


Recalling Firm/ Manufacturer
Carefusion 2200 Inc
75 N Fairway Dr
Vernon Hills, Illinois 60061-1845

For Additional Information Contact
CareFusion Customer Support
800-323-9088

Manufacturer Reason for Recall
The CareFusion AirLife Heated Infant Breathing Circuit is being recalled due to a regulatory compliance risk involving a material change. The changes to the gas pathway may potentially impact the safety of the device and quality of the gas condensates to the patient.

FDA Determined Cause
PREMARKET APPROVAL: No Marketing Application

Action
CareFusion sent an URGENT: PRODUCT RECALL letters dated July 31, 2014 to all affected customers. The letters instructed customers to: 1) perform a 100% physical inventory to verify if any of the affected product codes are in stock; 2) complete and return the attached Recall Response Form within 15 days; 3) notify any customers/parties that the recalled products were distributed to of the recall; 4) distributors should have all their customers return the products and a completed Recall Response Form to the distributor for credit, and, 5) customers should destroy the recalled products according to their disposal procedure. If a customers procedure(s) does not allow for the destruction of the recalled products, the customers was advised to contact CareFusion AirLife Customer Support at 800-323-9088 (Monday - Friday, 8:00 AM - 5:00 PM CST) for product return options. Customers will receive credit for all destroyed products. Direct accounts with questions about this recall should contact CareFusion AirLife Customer Support at 800-323-9088 (Monday - Friday, 8:00 AM - 5:00 PM CST) for additional information.

Quantity in Commerce
Approximately 318,280 devices

Distribution
Worldwide Distribution - US Nationwide in the states of AZ, CA, FL, IL, KY, LA, MI, MO, NE, NY, OH, OK, PA, RI, TN, TX, UT including Puerto Rico and the countries of Canada, China, Kuwait, Mexico, Saudi Arabia, and Switzerland.

Total Product Life Cycle
TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 57.55
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.