Class 1 Recall
Hudson RCI Neonate Manual Resuscitator

Date Posted: June 24, 2015
Recall Status: Open
Recall Number: Z-1809-2015
Recall Event ID: 7125424
Premarket Notification 510(K) Number: K06471925

Product Classification: Ventilator, Emergency, Manual (Resuscitator) - Product Code B7M

Product: Lifesaver Single Patient Use Manual Resuscitator Product Usage: The Hudson RCI Lifesaver Single Patient Use manual resuscitator with pressure monitoring port is a disposable medical device intended for use on patients requiring temporary augmentation of ventilation with or without supplemental oxygen delivery during episodes of acute ventilatory failure or insufficiency.

Code Information: Product Code 5361 - 6 Digit Lot No. 140514 - 4 Digit Lot No. 1420; 6 Digit Lot No. 140616 4
Digit Lot No. 1425, 6 Digit Lot No. 140817 4 Digit Lot No. 1425; 6 Digit Lot No. 140621 4
Digit Lot No. 1425, 6 Digit Lot No. 140806 4 Digit Lot No. 1432; 6 Digit Lot No. 141103 4
Digit Lot No. 1445; 6 Digit Lot No. 141117 - No. 4 Digit Lot No. 1447; 6 Digit Lot No. 141201-4
Digit Lot No. 1449; 6 Digit Lot No. 141224 - 4 Digit Lot No. 1452; 6 Digit Lot No. 141227 - 4
Digit Lot No. 1452; 6 Digit Lot No. 150112 - 4 Digit Lot No. 1503; Product Code 5562 - 6
Digit Lot No. 140504 - 4 Digit Lot No. 1419; 6 Digit Lot No. 140515 - 4 Digit Lot No. 1420; 6
Digit Lot No. 140517 - 4 Digit Lot No. 1420; 6 Digit Lot No. 140617 - 4 Digit Lot No. 1425; 6
Digit Lot No. 140621 - 4 Digit Lot No. 1425; No. 6 Digit Lot No. 140812 - 4 Digit Lot No. 1433; 6
Digit Lot No. 140819 - 4 Digit Lot No. 1434; 6 Digit Lot No. 140823 - 4 Digit Lot No. 1434; 6
Digit Lot No. 140929 - 4 Digit Lot No. 1440; 6 Digit Lot No. 141110 - 4 Digit Lot No. 1446; 6
Digit Lot No. 141115 - 4 Digit Lot No. 1446; 6 Digit Lot No. 141201 - 4 Digit Lot No. 1449; 6
Digit Lot No. 141214 - 4 Digit Lot No. 1451; 6 Digit Lot No. 150112 - 4 Digit Lot No. 1503;
Product Code 5364 - 6 Digit Lot No. 140507 - 4 Digit Lot No. 1419; 6 Digit Lot No. 140508 4
Digit Lot No. 1419; 6 Digit Lot No. 140514 - 4 Digit Lot No. 1420; 6 Digit Lot No. 140608 - 4
Digit Lot No. 1424; 6 Digit Lot No. 140614 - 4 Digit Lot No. 1424; 6 Digit Lot No. 140623 - 4
Digit Lot No. 1426; 6 Digit Lot No. 140629 - 4 Digit Lot No. 1426 - No. 6 Digit Lot No. 140714 - 4
Digit Lot No. 1429; 6 Digit Lot No. 140719 - 4 Digit Lot No. 1429; 6 Digit Lot No. 140806 - 4
Digit Lot No. 1432; 6 Digit Lot No. 140809 4 Digit Lot No. 1432; Product Code 5466 - 6 Digit
Lot No. 140520 - 4 Digit Lot No. 1421; 6 Digit Lot No. 140923 - 4 Digit Lot No. 1439; 6 Digit
Lot No. 140524 - 4 Digit Lot No. 1439; Product Code 4582 - 6 Digit Lot No. 140317 - 4 Digit
Lot No. 1412; 6 Digit Lot No. 140630 - 4 Digit Lot No. 1427; 6 Digit Lot No. 141013 - 4 Digit
Lot No. 1442.

Recalling Firm/Manufacturer: Teleflex Medical
Location: 2217 Weck Dr.
Research Triangle Park, North Carolina 27709-0186

For Additional Information Contact: Jennifer E. Suh
Phone: 610-378-0131

Manufacturer Reason for Recall: The intake port may be blocked which can cause the bag to fail to fill.

FDA Determined: COMPONENT CONTROLS (GMP - GOOD MANUFACTURING PRACTICE):
Cause 2  
Nonconforming Material/Component

Action  
Teleflex Medical sent an Urgent Medical Device Recall Notification letter dated May 14, 2015, to all consignees asking them to immediately discontinue distribution and quarantine the recalled product. The letter also requested a sub-recall of the product. The recall letter also included a response form which is to be returned to Teleflex by emailing it to recall@teleflex.com or fax it to 1-855-419-8507. Attn: Customer Service. Customers with questions were instructed to contact their local sales representative or Customer Service at 1-866-246-6990. For questions regarding this recall call 610-378-0131.

Quantity in Commerce  
9,333 units

Distribution  
Worldwide Distribution - US Nationwide in the states of AL, AK, AZ, AR, CA, CO, CT, FL, GA, IL, IA, KS, LA, MA, MI, MN, MS, MO, NE, NH, NY, NC, OH, OK, PA, RI, SD, TN, TX, VA, WA, including Puerto Rico and the countries of Australia, Bahamas, Canada, Guatemala, and Mexico.

Total Product Life Cycle  
TPLC Device Report29

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.5526
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

510(K) Database  
510(K) Is with Product Code = BTM and Original Applicant = HUDSON RESPIRATORY CARE, INC.30

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
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8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.cfm
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
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12. /scripts/cdrh/cfdocs/cfPMA/pma.cfm
13. /scripts/cdrh/cfdocs/cfHDE/hde.cfm
14. /scripts/cdrh/cfdocs/cfPCD/classification.cfm
15. /scripts/cdrh/cfdocs/cfStandards/search.cfm
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17. /scripts/cdrh/cfdocs/cfPCD_RH/classification.cfm
18. /scripts/cdrh/cfdocs/cfAssem/assembler.cfm
19. /scripts/cdrh/cfdocs/Medsun/searchReportText.cfm
20. /scripts/cdrh/cfdocs/cfClna/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
22. /scripts/cdrh/cfdocs/cfTPLC/inspect.cfm
24. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=71254
25. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?ID=K964719