Class 1 Device Recall Skintact Electrodes for Defibrillation

Date Initiated by Firm: September 01, 2016
Create Date: October 14, 2016
Recall Status: Open, Classified
Recall Number: Z-0004-2017
Recall Event ID: N018123
510(K) Number: K14280324
Product Classification: Automated external defibrillators (non-wearable) - Product Code MKJ
Product: Skintact Electrodes for Defibrillation, DF29N.

Product Usage:
Multifunction electrode for external defibrillation, pacing, cardioversion, and monitoring. The device is non-sterile and for single use only.

Code Information:
US: 60082-0774; 60082-0779; 60308-0777; 60114-0773; 51023-0775; 50904-0777; 50403-0778; 50130-0777; 41023-077; 41006-0778; 40730-0778; 40618-0778; and, 40130-0776.
Outside US: 60725-0774; 60620-0776; 60602-0774; 60052-0779; 60038-0771; 60114-0773; 51023-0775; 50904-0777; 50403-0778; 40827-0777; 40730-0778; 40618-0778; and, 40130-0776.

Recalling Firm/Manufacturer:
Leonhard Lang Medizintechnik GmbH
Archenweg 56
Innsbruck Austria

Manufacturer Reason for Recall:
There is a risk that defibrillation electrodes model DF29N will be connected with the defibrillator Welch Allyn AED 10 only with delay or not at all. This may cause a situation in which a patient, who is in a life threatening condition and requires a defibrillation shock, cannot be treated in good time.

FDA Determined Cause:
Device Design

Action:
Consignees were sent via email a Leonhard Lang “Important Safety Notice” dated September 1, 2016. The letter described the product being recalled. Description of the defect, Actions and time frame of the recall, & Compensation for the recalled electrodes. Advised consignees to inform all users within their organizations of the recall; and, secure and destroy the unused electrodes in their inventory. Confirmation of destruction can be done by completing and returning the “Confirmation of Destruction / Consumption” form by October 14, 2016. If the product was further distributed, they were to forward a copy of the Safety Notice. For questions contact sales staff.

Quantity in Commerce:
11,110 (US 8,040; OUS 3,070)

Distribution:
Worldwide Distribution - US, to the state of Florida, and, the countries of South Africa, Germany, Slovenia, France, United Arab Emirates, Great Britain, Italy, Israel, Serbia, Thailand, Thailand, South Africa, Lebanon, and Poland.

Total Product Life Cycle:
TPLC Device Report

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=149595
11/7/2016
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.

Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.

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 = MKJ and Original Applicant = Leonhard Lang GmbH

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm
8. /scripts/cdrh/cfdocs/cfpmn/denovo.cfm
9. /scripts/cdrh/cfdocs/cfRL/rl.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/cfClia/Search.cfm
21. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm
23. /scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&event_id=75181
24. /scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=K142803
25. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MKJ
26. /scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=MKJ
27. /scripts/cdrh/cfdocs/cfTPLC/tplc.cfm?id=MKJ
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=MKJ&knumber=&applicant=Leonhard%20Lang%20GmbH

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