FDA

Class 1 Device Recall Skintact Electrodes for Defibrillation

See Related Information 22

Date Initiated by Firm	September 01, 2016
Create Date	October 14, 2016
Recall Status[1]	Open[3], Classified
Recall Number	Z-0004-2017
Recall Event ID	75181[23]
510(K)Number	K142803[24]
Product Classification	Automated external defibrillators (non-wearable)[25] - **Product Code** MKJ[26]
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: 60602-0774; 60502-0779; 60308-077; 60114-0773; 51023-0775; 50904-0777; 50403-0778; 50130-0777; 41023-077; 41008-0778; 40730-0778; 40618-0778; and, 40130-0776., Outside US: 60725-0774; 60620-0776; 60602-0774; 60502-0779; 60308-0771;, 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 [2]	Device Design
Action	Consignees was sent via e-mail 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[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.

510(K) Database 510(K)s with Product Code = MKJ and Original Applicant = Leonhard Lang GmbH[29]

Links on this page:

1. http://www.addthis.com/bookmark.php?u508=true&v=152&username=fdamain
2. http://www.addthis.com/bookmark.php
3. http://www.fda.gov/default.htm
4. http://www.fda.gov/MedicalDevices/default.htm
5. http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Databases/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
10. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm
11. /scripts/cdrh/cfdocs/cfRES/res.cfm
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
16. /scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm
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
22. http://www.fda.gov/safety/recalls/enforcementreports/default.htm
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
28. http://www.fda.gov/MedicalDevices/Safety/ListofRecalls/ucm329946.htm
29. /scripts/cdrh/cfdocs/cfPMN/pmn.cfm?start_search=1&productcode=MKJ&knumber=&applicant=Leonhard%20Lang%20GmbH

Page Last Updated: 11/05/2016

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