Class 2 Device Recall DeRoyal (R) Cardiac Hypothermia Tray

Date Posted: July 29, 2014
Recall Status: Open
Recall Number: Z-2125-2014
Recall Event ID: 6874322
Product: DeRoyal (R) Cardiac Hypothermia Tray, REF 90-9422.07, 1 Per Pack, Rx Only
STERILE EO, Distributed by: DeRoyal Industries, Inc. 200 DeBusk Lane, Powell, TN 37849, USA; Made in Guatemala
Code Information: Lot Numbers: 30375880, 30515347, 30927891, 32922641, 336555641
Recalling Firm/Manufacturer: DeRoyal Industries Inc
200 DeBusk Ln
Powell, Tennessee 37849-4703
For Additional Information Contact: Tracy Edmundson
865-562-2334
Manufacturer Reason for Recall: The firm distributed surgical kits which contained irrigation sets which were subsequently recalled by Hospira.
Action: The recall was initiated by letter delivered via UPS on 6/4/2014. The firm requested that the consignee contact Stericycle to arrange for return and replacement of the product. A second notice was sent on 7/22/2014 to those accounts who did not respond to the initial notice. Distributors were requested to notify their end-users or provide a list of end-users to DeRoyal for direct notification. Effectiveness checks will be sent via email for those customers who have provided an email contact and via UPS for those customers who have not responded.
Quantity in Commerce: 230 units
Distribution: Distributed in the states of MI, GA, OH, IL, MO, and IN.

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55.

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/cfRL/rl.cfm
9. /scripts/cdrh/cfdocs/cfMAUDE/TextSearch.cfm