الموضوع: إشعار بمتابعة جهاز طبي مغروس
Thera Pearl 3-in-1 Breast Therapy

الجهاز المعني بالمتابعة:
- Thera Pearl 3-in-1 Breast Therapy
- Trade Mark: Lansinoh Laboratories
- Local Representative:

FDA بناء على التقرير الصادر عن وكالة ال
الذي يحذر فيه من استعمال الصفن المذكور أعلاه نظرا لوجود خلل في طريقة عمله، نرجو منكم
متاحب هذا الموضوع مع الأطباء الاختصاصيين والعمل بموجب التوصية الصادرة.

مرفق ربط:
- التقرير الصادر عن وكالة ال

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Class 2 Recall

THERA PEARL 3-in-1 BREAST THERAPY

Date Posted
February 04, 2013

Recall Number
Z-0764-2013

Product
THERA PEARL 3-in-1 BREAST THERAPY, 2 hot and cold packs in plastic box. The Thera Pearl 3-in-1 Breast Therapy is a reusable therapeutic hot and cold pack for use with pain, swelling, engorgement, plugged ducts or mastitis associated with breast feeding or to help encourage let-down while using a breast pump.

Code Information
Lot Numbers 100/12/01, 116/12/01, 108/12/01, 109/12/01, 149/12/01

Recalling Firm/Manufacturer
Lansinoh Laboratories Inc
333 N Fairfax St Ste 400
Alexandria, Virginia 22314-2632

For Additional Information Contact
Richard Thorne
703-299-6477

Reason for Recall
The Spanish translation on the instructions for Use (IFU) insert and product package for hot and cold packs has incorrect heating instructions which would cause product to over heat.

Action
Lansinoh Laboratories, Inc. sent an Urgent Product Recall letter dated August 14, 2012, to all affected customer. The letter identified the product, the problem, and the action to be taken by the customer. Customers were instructed to stop distributing and quarantine the affected product. Customers were informed that a credit would be issued for the affected product and they were asked to mail the postage paid Business Reply Card even if they do not have the affected product. If necessary call 1-877-366-1182 to arrange pickup. For questions customers were instructed to call the Customer Service Center at 1-800-292-4794. For questions regarding this recall call 703-299-6477.

Quantity in Commerce
51,472 units

Distribution
Nationwide Distribution, including the states of TX, CA, NJ, NY, SD, RI, WV, IL, PA, NC and MN.

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Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. ./cPMMN/pmm.cfm
8. ./cRUL/r1.cfm
9. ./cMAUDE/TextSearch.cfm
10. ./cRES/res.cfm
11. ./cPMA/pma.cfm
12. ./cPCCD/classification.cfm
13. ./cSTANDARDS/search.cfm
14. ./cCFR/cFRSearch.cfm
15. ./cPCCD_RH/classification.cfm
16. ./cAssem/assembler.cfm
17. ./Medsun/searchReportText.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=115101

4/29/2013