الموضوع: إشعار بمبادرة جهاز طبي
Liko Standard Slingbar 450

الجهاز المعني بالمنابة:
- Liko Standard Slingbar 450
- Trade Mark: Hill Rom Inc
- Local Representative:

FDA

بناء على التقرير الصادر عن وكالة ال
الذي يحذر فيه من استعمال الصنف المذكور أعلاه بسبب وجود خلل في عمله مما قد يؤثر على
سلامة المريض، نرجو منكم تعميم هذه النشرة على جميع المستشفيات المعنية.

مرفق ربط:
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- المستشفيات الحكومية
- المحفوظات

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 budding letters.png

Rue de la Musée - Imn. Hussein Mansour - Beyrouth, Liban - Tel.: 961.1.615724 - 615725 - Fax: 961.1.615730 - Email: directorgeneral@moph.gov.lb
U.S. Food & Drug Administration

Medical & Radiation Emitting Device Recalls

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Class 2 Recall
Liko Standard Slingbar 450.

Date Posted
December 31, 2012

Recall Number
Z-0622-2013

Product
Liko Standard Slingbar 450. The Standard Slingbar 450 is a versatile sling bar which can be used for most lifting situations. It can be used with different Liko ceiling and mobile lifts.

Code Information
The Liko Standard Slingbar 450 accessory has been supplied under multiple product numbers and co-branded with the sale of mobile lifts. The Standard Slingbar 450 is not serialized and has been distributed between January 1990 and the present. Here are the different Product Numbers in which the Slingbar has been shipped under: Standard Slingbar 450: 20060029, 20190024, 20180041, 31190015, 31290017, 31290043, 31560001, 31560003, 31560007, 3156014, 3156016, 31560044, and 5019013. Packaged with Wolkop to April of 2005: 20060001, 20060005, 2000006, 20000007, 20000009, 2000009G, 200000D, 2000000K, 2000000E, 20000003F, 20000009F, 20000009J, 20000009N, 2000000UR, 2000000JU, 200000010, 20000100K, 20000100U, 20000101F, 20000101N, 20000101H, 20000101J, 20000101N, 20000101H, 20000101J, 20000101N, 20000101H, 20000101J, 20000101N, 20000101H, 20000101J, 20000101N.

Recalling Firm/
Manufacturer
Hi-Rom, Inc.
1089 State Route 46 East
Balesville, Indiana 47067-7520

Reason for
Recall
Liko-Hi-Rom has received reports from facilities which indicate that serious injuries have been received related to the Standard Slingbar 450. There have been 6 complaints of injury related to the product over the past 32 years (6 out of 838,697,155 estimated patient uses). One of the injuries was associated with a patient during use, four injuries occurred when the slingbar was not in use when

Action
Hi-Rom sent an URGENT MEDICAL DEVICE RECALL notification letter dated December 6, 2012, to all affected customers. The letter identified the product the problem and the action needed to be taken by the customer. Customers were requested to please read, fill in completely, and return the Response Form to Hi-Rom immediately. This information will be compiled and reported to the applicable regulatory governing bodies. If we do not receive your response we will be required to contact you asking for your response. Continue to follow safe lifting practices, and do not allow unauthorized persons, especially children, to play around or operate the lift. If you have any questions concerning this Customer Safety Notification, please contact Hi-Rom Technical Support at 800-445-3720.

Quantity in Commerce
261 units

Distribution
Wide Distribution - US (nationally) including the states of AR, AZ, CA, CO, FL, GA, HI, IA, IL, IN, KS, KY, MA, ME, MI, MN, MO, MS, NC, NE, NJ, NM, NV, NY, OH, OR, PA, TN, TX, UT, WA, WV, and WI, and the country Canada. We have not yet defined our European or International facilities at this time.

Links on this page:
4. http://www.fda.gov/MedicalDevices/default.htm
6. /scripts/cdrh/devicesatfda/index.cfm
7. /cfrDMM/pmn.cfm

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=110438
1/14/2013