Class 2 Device Recall mcompass 2channel Balloon Catheters

Date Initiated by Firm: June 14, 2017
Create Date: August 25, 2017
Recall Status: Open, Classified
Recall Number: Z-3072-2017
Recall Event ID: 7770623
510(K)Number: K120088 K143031
Product Classification: Catheter, rectal - Product Code GBT
Product: mcompass 2-channel Balloon Catheters

The mcompass Biofeedback Anorectal Manometry System is for use on patients requiring anorectal pressure studies. mcompass Anorectal Manometry System (RMD-001-001) which includes a FOB component connected to the balloon catheter to inflate and deflate and a medical grade tablet PC to run the software. The software is not included in the recall, only the balloon catheter component.

Code Information: Part # RMD-002-004, Lot No #'s 160627-10 and 160627-11.
Recalling Firm/Manufacturer: Medspira, LLC
2718 Summer St NE
Minneapolis MN 55413-2820
For Additional Information Contact: Paul Bradik
612-789-0013
Manufacturer Reason for Recall: Potential failure in the balloon bond in the inner catheter stem, leading to the separation of the balloon from the inner stem, leaving it in the rectal cavity.
FDA Determined Cause: Employee error
Action: The firm Medspira plans to contact all foreign and domestic consignees in regards to the recall. International consignees are to destroy recalled product by cutting the catheter shaft and balloon with scissors. It is also requested that their own customers be notified of the recall. Medspira plans to provide product replacement. Domestic customers are asked to return affected catheters to the recalling firm. Medspira indicates that they will cover shipping costs and replacements. All consignees are asked to complete and return the attached recall response form. For further questions please call, (612) 789-0013.

Quantity in Commerce: 355 catheters (255 US - 100 foreign.)
Distribution: Worldwide Distribution - US Distribution to the states of: CA, FL, IA, ID, and TX, and to the countries of: Austria, Italy, Malaysia, Philippines, Sweden, and United Kingdom
Total Product Life Cycle: TPLC Device Report

1 A record in this database is created when a firm initiates a correction or removal action. The record is updated if the FDA

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=157691
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