Class 2 Recall Zippie IRIS Wheelchair

Date Posted: August 25, 2015
Recall Status: Open
Recall Number: Z-2466-2015
Recall Event ID: 71829
Premarket Notification 510(K) Number: K123975
Product Classification: Wheelchair, Mechanical - Product Code IOR
Product: Zippie IRIS Wheelchair, model E1Z5A in combination with option code 188M02 - MONO Backrest system with Dynamic Backrest option. Provide mobility to persons limited to a sitting position.
Code Information: Model E1Z51, serial number range - ZRS-042132 to ZRS-042157.
Recalling Firm/Manufacturer: Sunrise Medical (US) LLC
2842 N Business Ave
Fresno, California 93727-1328
For Additional Information Contact: Laurie H. Roberts, M.S. RAC
559-348-2572
Manufacturer Reason for Recall: Quickie IRIS and Zippie IRIS tilt-in-space wheelchairs with MONO Backrest System with Dynamic Backrest may break over time resulting in a fall or injury to occupant.
FDA Determined Cause: DESIGN: Device Design
Action: Sunrise Medical sent an Urgent Medical Device Field Correction letter dated July 27, 2015, to all affected dealers. The letter identified the product, the problem, and the action to be taken by the dealer. Dealers were instructed to immediately contact their customers to make arrangements to have the correction made with a replacement kit which will be supplied by Sunrise Medical to each dealer. Each dealer is requested to send back to Sunrise Medical the Acknowledgment and Response Form(s) by fax, email or regular mail once the work is completed. Customers with questions were instructed to contact Sunrise Medical Regulatory Affairs at (888) 208-4901.
Quantity in Commerce: 64 total wheelchairs, both models
Distribution: Worldwide Distribution - US (nationwide) and Internationally to Australia, Germany and Canada.
Total Product Life Cycle: TPLC Device Report

1 For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55
2 Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall.
510(K) Database: 510(K)s with Product Code = IOR and Original Applicant = SUNRISE MEDICAL

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=139170
9/7/2015