Class 2 Recall
Quickie IRIS Wheelchair

See Related Information[23]

Date Posted	August 26, 2015
Recall Status[1]	Open
Recall Number	Z-2467-2015
Recall Event ID	71829[24]
Premarket Notification 510(K) Number	K123975[25]
Product Classification	Wheelchair, Mechanical[26] - **Product Code** IOR[27]
Product	Quickie IRIS Wheelchair. model EIZ4-2 in combination with option code 183M02 - MONO Backrest system with Dynamic Backrest option. Provide mobility to persons limited to a sitting position.
Code Information	Model EIZ4-2, serial number range - IRS-046185-IRS-063437 and IRSE-058994 to IRSE-063928.
Recalling Firm/ Manufacturer	Sunrise Medical (US) LLC 2842 N Business Park 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 [2]	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[28]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[29]
[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[30]