

FDA Home³ Medical Devices⁴ Databases⁵

Class 2 Device Recall Zippie IRIS Wheelchair

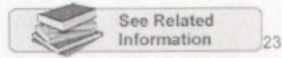


6 510(k) | DeNovo⁶ | Registration & Listing⁹ | Adverse Events¹⁰ | Recalls¹¹ | PMA¹² | HDE¹³ | Classification¹⁴ | Standards¹⁵
 CFR Title | Radiation-Emitting Products¹⁷ | X-Ray Assembler¹⁸ | Medsun Reports¹⁹ | CLIA²⁰ | TPLC²¹ | Inspections²²
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**Class 2 Recall
Zippie IRIS Wheelchair**



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|---|---|
| Date Posted | August 26, 2015 |
| Recall Status¹ | Open |
| Recall Number | Z-2466-2015 |
| Recall Event ID | 71829²⁴ |
| Premarket Notification 510(K) Number | K123975²⁵ |
| Product Classification | Wheelchair, Mechanical²⁶ - Product Code IOR²⁷ |
| Product | Zippie IRIS Wheelchair, model EIZ5A 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 EIZ51, serial number range - ZRS-042132 to ZRS-042157. |
| 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 Cause² | 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 Report²⁸ |

¹ For details about termination of a recall see [Code of Federal Regulations \(CFR\) Title 21 §7.55²⁹](#)

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 MEDICAL³⁰](#)