Class 2 Recall RTH8 Rotor

See Related Information[22]

Date Posted	December 23, 2014
Recall Status[1]	Open
Recall Number	Z-0857-2015
Recall Event ID	69946[23]
Product Classification	Centrifuges (Micro, Ultra, Refrigerated) For Clinical Use[24] - **Product Code** JQC[25]
Product	RTH8 Rotor, P/N X01-005847-001. RTH8 used in the StatSpin Express 4 Horizontal Centrifuge, Model M510, Product No. SSH4. The RTH8 rotor is used with the Statspin Express 4 Horizontal Centrifuge. StatSpin Express 4 Centrifuge: For in vitro diagnostic use to produce the rapid separation of whole blood contained in original collection tubes.
Code Information	Serial No. 3100 through 7012
Recalling Firm/ Manufacturer	Iris Diagnostics 9172 Eton Ave Chatsworth, California 91311-5805
Manufacturer Reason for Recall	Iris International is recalling the RTH8 Rotor used in the StatSpin Express 4 Horizontal Centrifuge because the RTH8 rotor may develop cracks with use over time.
FDA Determined Cause [2]	DESIGN: Component Design/Selection
Action	A customer notification letter dated 12/3/14 was sent to all customers to inform them that Iris International is recalling the RTH8 Rotor used in the StatSpin Express 4 Horizontal Centrifuge because the RTH8 rotor may develop cracks with use over time. The letter informs the customers of the problems identified and the actions to be taken. Beckman Coulter will be managing the logistics of the recall notice. Customers with questions are instructed to contact Customer Technical Support at (800) 854-3633 or via website at http://www.beckmancoulter.com.
Quantity in Commerce	3912 units
Distribution	Worldwide Distribution-US (nationwide) including Puerto Rico and the countries of Australia, Austria, Belgium, Canada, China, Colombia, Czech Republic, Denmark, Finland, France, Germany, Greece, Hong Kong, Hungary, Indonesia, Ireland, Israel, Italy, Japan, Korea, Kuwait, Lebanon, Malaysia, Mexico, Netherlands, New Zealand, Norway, Portugal, Romania, Slovakia, South Africa, Spain, Sweden, Switzerland, Taiwan, Thailand, Turkey, United Kingdom, and Venezuela.
Total Product Life Cycle	TPLC Device Report[26]

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[27]
[2] Per FDA policy, recall cause determinations are subject to modification up to the point of termination of the recall

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