Class 2 Device Recall Cordis EMPIRA RX PTCA Dilatation Catheter

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See Related Information[21]

Date Posted	June 11, 2014
Recall Status[1]	Open
Recall Number	Z-1784-2014
Recall Event ID	64273[22]
Product	Cordis EMPIRA RX PTCA Dilatation Catheter Catalog # 85R30300S For cardiovascular use.
Code Information	Catalog # 85R30300S LOT # CE0001447 exp date: 2014-08
Recalling Firm/ Manufacturer	Cordis Corporation 14201 Nw 60th Ave Miami Lakes, Florida 33014-2802
Manufacturer Reason for Recall	Dilatation catheters could exhibit radial versus axial tears should they burst during inflation.
Action	An Urgent Medical Device Recall letter and Acknowledgement form was sent overnight to mulitple contacts in each account February 7, 2013. A representative will follow-up as necassary to facility obtaining signature, faxing the acknowledgment form to Cordis, collecting and returning units.
Quantity in Commerce	80 units
Distribution	Worldwide distribution: US states: AZ, FL, IL, LA, MA, NJ, OR, SC, and TX. Armenia, Austria, Belgium, Colombia, Czech Republic, France, Hungary, Iran, Israel, India, Italy, Kuwait, Latvia, Lebanon, Luxembourg, Mexico, Morocco, Poland, Portugal, Russia, Saudi Arabia, South Africa, Spain, Switzerland, and United Arab Emirates.

[1] For details about termination of a recall see Code of Federal Regulations (CFR) Title 21 §7.55[23]

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