

K142364 Barrx RFA Self Sizing Balloon CatheterOct 1, 2014
37 days to decisionK142364 · Product code: **GEI** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k142364/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 25, 2014
Decision date	Oct 1, 2014
Days to decision	37 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Rachel Silva
510(k) history	88 submissions · 85 cleared · 2010-2026

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