FDA 510(k) Premarket Notification

K150251 Barrx Anorectal RFA Wand

CLEARED

Jul 28, 2015
175 days to decision

K150251 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k150251/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 3, 2015
Decision date	Jul 28, 2015
Days to decision	175 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k150251/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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