FDA 510(k) Premarket Notification

K162802 Barrx Anorectal RFA Wand

CLEARED

Jan 24, 2017
111 days to decision

K162802 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k162802/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Oct 5, 2016
Decision date	Jan 24, 2017
Days to decision	111 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/k162802/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 1, 2026