FDA 510(k) Premarket Notification

K160290 Valleylab REM Polyhesive Infant Patient Return Electrode

CLEARED

May 19, 2016
106 days to decision

K160290 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k160290/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 3, 2016
Decision date	May 19, 2016
Days to decision	106 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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