FDA 510(k) Premarket Notification

K172535 Bipolar applicator CELON ProCurve V

CLEARED

Nov 16, 2017
86 days to decision

K172535 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k172535/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 22, 2017
Decision date	Nov 16, 2017
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Olympus Winter & Ibe GmbH**
Location	Melville, NY, US
Contact	Jan-Oliver Upmeier
510(k) history	42 submissions · 42 cleared · 1997-2025