FDA 510(k) Premarket Notification

CLEARED

K200146 HET Bipolar Electrocautery Forceps, HET Bipolar Electrocautery Monitor

May 7, 2020
106 days to decision

K200146 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200146/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 22, 2020
Decision date	May 7, 2020
Days to decision	106 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Covidien, LLC**
Location	Mansfield, MA, US
Contact	Shani Frenkel
510(k) history	89 submissions · 86 cleared · 2010-2026