FDA 510(k) Premarket Notification

CLEARED

K191612 Encision AEM Monopolar Laparoscopic Instruments and Accessories

Mar 20, 2020
277 days to decision

K191612 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k191612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jun 17, 2019
Decision date	Mar 20, 2020
Days to decision	277 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Encision Incorporated**
Location	Boulder, CO, US
Contact	Denise Baker
510(k) history	1 submissions · 1 cleared · 2020-2020

REGULATORY CONSULTANT

Consulting firm	**Hart Consulting, LLC**
Contact	Charles M. (Mike) Hart

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov