FDA 510(k) Premarket Notification

K192518 Reusable Monopolar Active Cord

CLEARED

Oct 25, 2019
42 days to decision

K192518 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k192518/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 13, 2019
Decision date	Oct 25, 2019
Days to decision	42 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Us Endoscopy**
Location	Mentor, OH, US
Contact	Gregory Land
510(k) history	1 submissions · 1 cleared · 2019-2019