FDA 510(k) Premarket Notification

K200931 RF Surgical Generator

CLEARED

Nov 24, 2020
231 days to decision

K200931 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k200931/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 7, 2020
Decision date	Nov 24, 2020
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Fulwell, LLC**
Location	Miami, FL, US
Contact	Perla Melisa Mcliberty
510(k) history	2 submissions · 2 cleared · 2019-2020

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Keda Biological Tech Co., Ltd.**
Contact	Jet Li

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