FDA 510(k) Premarket Notification

K183564 Electrosurgical Generator

CLEARED

Jun 13, 2019
175 days to decision

K183564 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k183564/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Dec 20, 2018
Decision date	Jun 13, 2019
Days to decision	175 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Guangzhou Keda Testing 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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k183564/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026