FDA 510(k) Premarket Notification

K230539 ArtiSential Laparoscopic Instruments-Electrodes

CLEARED

Apr 27, 2023
59 days to decision

K230539 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k230539/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Feb 27, 2023
Decision date	Apr 27, 2023
Days to decision	59 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Livsmed, Inc.**
Location	Seongnam-Si, KR
Contact	Dong Wook Lee
510(k) history	12 submissions · 12 cleared · 2020-2025

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k230539/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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