FDA 510(k) Premarket Notification

CLEARED

K241138 ArtiSeal Vessel Sealing System-ArtiSeal Instruments

Nov 15, 2024
205 days to decision

K241138 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k241138/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 24, 2024
Decision date	Nov 15, 2024
Days to decision	205 days
Third-party review	Yes
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	ArtiSeal Vessel Sealing System-ArtiSeal Generator

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**Third Party Review Group, LLC**
Contact	Dave Yungvirt

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