FDA 510(k) Premarket Notification

K232947 SIRA™ RFA Electrosurgical Device

CLEARED

Dec 12, 2023
83 days to decision

K232947 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k232947/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 20, 2023
Decision date	Dec 12, 2023
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Innoblative Designs, Inc.**
Location	Chicago, IL, US
Contact	Katherine Crowley
510(k) history	2 submissions · 2 cleared · 2019-2023

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	Janice Hogan

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