FDA 510(k) Premarket Notification

K212107 Reverso

CLEARED

Nov 10, 2021
127 days to decision

K212107 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212107/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jul 6, 2021
Decision date	Nov 10, 2021
Days to decision	127 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Intelis Instruments , Ltd.**
Location	Hadera, IL
Contact	Amit Goren
510(k) history	1 submissions · 1 cleared · 2021-2021

REGULATORY CONSULTANT

Consulting firm	**A. Stein - Regulatory Affairs Consulting , Ltd.**
Contact	Amit Goren

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