FDA 510(k) Premarket Notification

K211000 ACUTRON

CLEARED

Jun 9, 2022
433 days to decision

K211000 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k211000/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Apr 2, 2021
Decision date	Jun 9, 2022
Days to decision	433 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Ilooda Co,., Ltd.**
Location	Gwonseon-Gu, Suwon-Si, KR
Contact	Yun-Jung Ha
510(k) history	16 submissions · 16 cleared · 2015-2024

REGULATORY CONSULTANT

Consulting firm	**Mtechgroup**
Contact	Dave Kim

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