FDA 510(k) Premarket Notification

K250657 gi2000 Electrosurgical Generator

CLEARED

Jun 3, 2025
90 days to decision

K250657 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250657/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Mar 5, 2025
Decision date	Jun 3, 2025
Days to decision	90 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Cintron Medical Corporation**
Location	Westminster, CO, US
Contact	William Bowers
Website	http://www.cintronmedical.com/
510(k) history	1 submissions · 1 cleared · 2025-2025