FDA 510(k) Premarket Notification

K233123 SILKRO

CLEARED

Jun 24, 2024
271 days to decision

K233123 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k233123/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Sep 27, 2023
Decision date	Jun 24, 2024
Days to decision	271 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Hironic Co., Ltd.**
Location	Gyeonggi-Do, KR
Contact	Gwijin Lee
510(k) history	8 submissions · 8 cleared · 2018-2026