FDA 510(k) Premarket Notification

K210084 SILKRO

CLEARED

Jun 3, 2022
507 days to decision

K210084 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k210084/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Jan 12, 2021
Decision date	Jun 3, 2022
Days to decision	507 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

REGULATORY CONSULTANT

Consulting firm	**E & M**
Contact	Sanghwa Myung

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k210084/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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