FDA 510(k) Premarket Notification

K213612 SYLFIRM X

CLEARED

Jun 23, 2022
220 days to decision

K213612 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k213612/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Nov 15, 2021
Decision date	Jun 23, 2022
Days to decision	220 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**VIOL Co., Ltd.**
Location	Seongnam-Si, KR
Contact	Chai Kyoung Woo
510(k) history	5 submissions · 5 cleared · 2017-2024

REGULATORY CONSULTANT

Consulting firm	**Gms Consulting**
Contact	Jong Hyun Kim

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