FDA 510(k) Premarket Notification

K242469 RFMagik Lite

CLEARED

Apr 25, 2025
248 days to decision

K242469 · Product code: **GEI** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k242469/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Electrosurgical, Cutting & Coagulation & Accessories (GEI)
Date received	Aug 20, 2024
Decision date	Apr 25, 2025
Days to decision	248 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Agnes Medical Co., Ltd.**
Location	Seongnam-Si, KR
Contact	Heui Kyeong Pak
510(k) history	7 submissions · 7 cleared · 2019-2025

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