FDA 510(k) Premarket Notification

K240518 swiftPro™ System

CLEARED

Apr 23, 2024
60 days to decision

K240518 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240518/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Feb 23, 2024
Decision date	Apr 23, 2024
Days to decision	60 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Emblation Limited**
Location	Stirling, GB
Contact	Mairi MacFadyen
Website	https://www.emblation.com
510(k) history	2 submissions · 2 cleared · 2024-2025

Emblation Limited is a leader in energy-based medical technology with a manufacturing facility in Stirling, GB. The company specializes in microwave technology for clinical and research applications across multiple medical specialties. Emblation has received FDA 510(k) clearances from total submissions since 2024. The company's cleared devices focus on General & Plastic Surgery applications. The latest clearance was in 2025, demonstrating continued regulatory activity and product innovation. The company's product portfolio includes the swiftPro System, a portable microwav...

REGULATORY CONSULTANT

Consulting firm	**Blackwell Device Consulting**
Contact	Angela Blackwell

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