FDA 510(k) Premarket Notification

K222388 swiftPro System

CLEARED

May 4, 2023
269 days to decision

K222388 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k222388/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Aug 8, 2022
Decision date	May 4, 2023
Days to decision	269 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Emblation , Ltd.**
Location	Alloa, GB
Contact	Mairi MacFayden
510(k) history	2 submissions · 2 cleared · 2018-2023

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k222388/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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