FDA 510(k) Premarket Notification

K250718 swiftPro System (SWF-SPS)

CLEARED

Aug 8, 2025
151 days to decision

K250718 · Product code: **NEY** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k250718/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Ablation, Microwave And Accessories (NEY)
Date received	Mar 10, 2025
Decision date	Aug 8, 2025
Days to decision	151 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	Swift System (SWF-SYS)

APPLICANT

Company	**Emblation Limited**
Location	Stirling, GB
Contact	Jack Ozer
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

CLINICAL EVIDENCE - NCT05371834

Microwave Treatment of Common and Plantar Warts

Status	Active not recruiting - *No results published to ClinicalTrials.gov*
Enrollment	119 patients (actual)
Study sites	6 sites
Condition studied	Warts
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Open label
Completion date	Mar 1, 2025
Sponsor	Blackwell Device Consulting (Industry)

Primary outcome

Clearance of all treated warts, each of which is defined as "resolved" or "not resolved" based on the classification by the blinded site investigator assessing the treated warts at three months post final treatment (up to 5 warts in total).

Secondary outcome

Clearance of all treated warts at three months post final treatment, each of which is defined as "lesion no longer visible" but assessed by the majority of three independent blinded assessors using photographs

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT05371834
