FDA 510(k) Premarket Notification

K240616 FAQ™ (102)

CLEARED

Jul 15, 2024
132 days to decision

K240616 · Product code: **PAY** · Physical Medicine
Source: https://www.510kdatabase.net/k240616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Radiofrequency Coagulation Device For Wrinkle Reduction (PAY)
Date received	Mar 5, 2024
Decision date	Jul 15, 2024
Days to decision	132 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Statement

APPLICANT

Company	**Foreo, Inc.**
Location	Las Vegas, NV, US
Contact	Evan Feldstein
510(k) history	10 submissions · 10 cleared · 2016-2026

REGULATORY CONSULTANT

Consulting firm	**DD Consulting**
Contact	Danijela Domljanovic

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