FDA 510(k) Premarket Notification

K240378 FAQ™ 201, FAQ™ 202

CLEARED

Apr 19, 2024
72 days to decision

K240378 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k240378/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Feb 7, 2024
Decision date	Apr 19, 2024
Days to decision	72 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