

K240378 FAQ™ 201, FAQ™ 202Apr 19, 2024
72 days to decisionK240378 · Product code: **OHS** · General & Plastic SurgerySource: <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](https://accessdata.fda.gov)510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k240378/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026