

**K240616 FAQ™ (102)**Jul 15, 2024  
132 days to decisionK240616 · Product code: **PAY** · Physical Medicine  
Source: <https://www.510kdatabase.net/k240616/>**SUBMISSION DETAILS**

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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**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>DD Consulting</b>
Contact	Danijela Domljanovic

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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k240616/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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