

K242796 CryoGlow (FW3XXXX)Nov 27, 2024
72 days to decisionK242796 · Product code: **OHS** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k242796/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Sep 16, 2024
Decision date	Nov 27, 2024
Days to decision	72 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Sharkninja Operating, LLC
Location	Needham, MA, US
Contact	Alyssa Aquino
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	Covington & Burling, Llp
Contact	Lynette Zentgraf

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

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