FDA 510(k) Premarket Notification

K244060 eCO2 3D

CLEARED

Jul 31, 2025
212 days to decision

K244060 · Product code: **ONG** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k244060/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Laser Surgical Instrument With Microbeamfractional Output (ONG)
Date received	Dec 31, 2024
Decision date	Jul 31, 2025
Days to decision	212 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Lutronic Corporation**
Location	North Reading, MA, US
Contact	Sarah Dunne
510(k) history	29 submissions · 29 cleared · 2007-2025

REGULATORY CONSULTANT

Consulting firm	**Cynosure, Inc.**
Contact	Sean Reynolds

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k244060/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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