

K250281 DEKA LOTUSFeb 26, 2025
26 days to decisionK250281 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k250281/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Jan 31, 2025
Decision date	Feb 26, 2025
Days to decision	26 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	EI.En S.P.A.
Location	Hopkinton, MA, US
Contact	Peruzzi Paolo
510(k) history	15 submissions · 15 cleared · 2014-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k250281/> 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 13, 2026