

K233473 DEKA LOTUSMay 16, 2024
204 days to decisionK233473 · Product code: **ONF** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k233473/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Powered Light Based Non-laser Surgical Instrument With Thermal Effect (ONF)
Date received	Oct 25, 2023
Decision date	May 16, 2024
Days to decision	204 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	Paolo Peruzzi
510(k) history	15 submissions · 15 cleared · 2014-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k233473/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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