FDA 510(k) Premarket Notification

K233473 DEKA LOTUS

CLEARED

May 16, 2024
204 days to decision

K233473 · Product code: **ONF** · General & Plastic Surgery
Source: 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	**El.En S.P.A.**
Location	Hopkinton, MA, US
Contact	Paolo Peruzzi
510(k) history	15 submissions · 15 cleared · 2014-2026