FDA 510(k) Premarket Notification

K223147 myLEDmask

CLEARED

May 14, 2023
221 days to decision

K223147 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223147/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Oct 5, 2022
Decision date	May 14, 2023
Days to decision	221 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Myblend**
Location	Neuilly-Sur-Seine, FR
Contact	Clédia Hettinger
510(k) history	1 submissions · 1 cleared · 2023-2023

REGULATORY CONSULTANT

Consulting firm	**Ceiso**
Contact	José Perez

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