FDA 510(k) Premarket Notification

K212275 Dermalux Flex MD

CLEARED

Nov 18, 2021
121 days to decision

K212275 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k212275/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Jul 20, 2021
Decision date	Nov 18, 2021
Days to decision	121 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Aesthetic Technology, Ltd.**
Location	Warrington, GB
Contact	Dale Needham
510(k) history	4 submissions · 4 cleared · 2020-2024

REGULATORY CONSULTANT

Consulting firm	**Richard Hamer Associates, LLC**
Contact	Richard Hamer

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