FDA 510(k) Premarket Notification

K223919 B.Light Clear Evo and B.Light Restore Evo

CLEARED

Sep 23, 2023
268 days to decision

K223919 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k223919/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Dec 29, 2022
Decision date	Sep 23, 2023
Days to decision	268 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Bemer Int AG**
Location	Triesen, LI
Contact	Sandra Schwarzenberger
510(k) history	4 submissions · 4 cleared · 2017-2023

REGULATORY CONSULTANT

Consulting firm	**ProMedic Consulting, LLC**
Contact	Paul Dryden

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

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k223919/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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