FDA 510(k) Premarket Notification

K072459 OMNILUX NEW-U

CLEARED

Mar 3, 2008
185 days to decision

K072459 · Product code: **OHS** · General & Plastic Surgery
Source: https://www.510kdatabase.net/k072459/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Aug 31, 2007
Decision date	Mar 3, 2008
Days to decision	185 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Photo Therapeutics, Inc.**
Location	Carlsbad, CA, US
Contact	SUE DARCY
510(k) history	2 submissions · 2 cleared · 2008-2009

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k072459/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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