

K183708 Poly ClearSep 17, 2019
260 days to decisionK183708 · Product code: **OLP** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k183708/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Over-the-counter Powered Light Based Laser For Acne (OLP)
Date received	Dec 31, 2018
Decision date	Sep 17, 2019
Days to decision	260 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Medtek Skincare, LLC
Location	Hudson, NY, US
Contact	Gary Richardson
510(k) history	2 submissions · 2 cleared · 2018-2019

REGULATORY CONSULTANT

Consulting firm	FDA Regulatory Consultants, LLC
Contact	Susan Anthony-Dewet

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

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