

K180875 POLY REJUVSep 14, 2018
164 days to decisionK180875 · Product code: **OHS** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k180875/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Light Based Over The Counter Wrinkle Reduction (OHS)
Date received	Apr 3, 2018
Decision date	Sep 14, 2018
Days to decision	164 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	Aegis Regulatory, Inc.
Contact	Susan Anthony-Dewet

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k180875/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 28, 2026