

K161455 Catalys Precision Laser SystemSep 20, 2016
117 days to decisionK161455 · Product code: **OOE** · Ophthalmic
Source: <https://www.510kdatabase.net/k161455/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	May 26, 2016
Decision date	Sep 20, 2016
Days to decision	117 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optimedica Corporation
Location	Laguna Beach, CA, US
Contact	Ankur Kaushal
510(k) history	8 submissions · 8 cleared · 2006-2016

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161455/> 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 2, 2026