

K220516 CATALYS Precision Laser systemMay 17, 2022
83 days to decisionK220516 · Product code: **OOE** · Ophthalmic
Source: <https://www.510kdatabase.net/k220516/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Feb 23, 2022
Decision date	May 17, 2022
Days to decision	83 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Amo Manufacturing USA, LLC
Location	Milpitas, CA, US
Contact	Alex Etlin
510(k) history	6 submissions · 6 cleared · 2015-2023

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k220516/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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