

K210701 CATALYS Precision Laser SystemApr 7, 2021
29 days to decisionK210701 · Product code: **OOE** · Ophthalmic
Source: <https://www.510kdatabase.net/k210701/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Mar 9, 2021
Decision date	Apr 7, 2021
Days to decision	29 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	Laarni Ricafort
510(k) history	6 submissions · 6 cleared · 2015-2023

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