

K223838 Catalys™ Precision Laser SystemApr 12, 2023
111 days to decisionK223838 · Product code: **OOE** · Ophthalmic
Source: <https://www.510kdatabase.net/k223838/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Dec 22, 2022
Decision date	Apr 12, 2023
Days to decision	111 days
Third-party review	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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