

**K182083 Catalys Precision Laser System**Nov 9, 2018  
99 days to decisionK182083 · Product code: **OOE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k182083/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmic Femtosecond Laser (OOE)
Date received	Aug 2, 2018
Decision date	Nov 9, 2018
Days to decision	99 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Amo Manufacturing USA, LLC</b>
Location	Milpitas, CA, US
Contact	James Patrick Garvey II
510(k) history	6 submissions · 6 cleared · 2015-2023

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k182083/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 27, 2026