

**K172002 Catalys Precision Laser System**Aug 25, 2017  
53 days to decisionK172002 · Product code: **OOE** · Ophthalmic  
Source: <https://www.510kdatabase.net/k172002/>**SUBMISSION DETAILS**

---

|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Ophthalmic Femtosecond Laser (OOE) |
| Date received         | Jul 3, 2017                        |
| Decision date         | Aug 25, 2017                       |
| Days to decision      | 53 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

---

|                |                                       |
|----------------|---------------------------------------|
| Company        | <b>Amo Manufacturing USA, LLC</b>     |
| Location       | Milpitas, CA, US                      |
| Contact        | Anita Xavier                          |
| 510(k) history | 6 submissions · 6 cleared · 2015-2023 |

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k172002/> 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