

K200056 Catalys Precision Laser SystemMay 18, 2020
126 days to decisionK200056 · Product code: **OOE** · Ophthalmic
Source: <https://www.510kdatabase.net/k200056/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Ophthalmic Femtosecond Laser (OOE) |
| Date received | Jan 13, 2020 |
| Decision date | May 18, 2020 |
| Days to decision | 126 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Amo Manufacturng USA, LLC |
| Location | Milpitas, CA, US |
| Contact | Laarni Ricafort |
| 510(k) history | 1 submissions · 1 cleared · 2020-2020 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k200056/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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