

K191846 MAXReach Laser ProbeDec 23, 2019
166 days to decisionK191846 · Product code: **HQB** · Ophthalmic
Source: <https://www.510kdatabase.net/k191846/>**SUBMISSION DETAILS**

| | |
|-----------------------|---------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Photocoagulator And Accessories (HQB) |
| Date received | Jul 10, 2019 |
| Decision date | Dec 23, 2019 |
| Days to decision | 166 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Vortex Surgical, Inc. |
| Location | Chesterfield, MO, US |
| Contact | Bob Neu |
| 510(k) history | 2 submissions · 2 cleared · 2019-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k191846/> Data sourced from FDA 510(k) public records (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. - Generated May 26, 2026