

K121675 VERSAVITJun 21, 2012
15 days to decisionK121675 · Product code: **HQE** · Ophthalmic
Source: <https://www.510kdatabase.net/k121675/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Vitreous Aspiration And Cutting, Ac-powered (HQE) |
| Date received | Jun 6, 2012 |
| Decision date | Jun 21, 2012 |
| Days to decision | 15 days |
| Third-party review | Yes |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Synergetics, Inc. |
| Location | Chesterfield, MO, US |
| Contact | DAN REGAN |
| 510(k) history | 16 submissions · 16 cleared · 1992-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121675/> 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 June 14, 2026