

K212763 UniVit HE, UniVit UHSAug 10, 2022
344 days to decisionK212763 · Product code: **HQE** · Ophthalmic
Source: <https://www.510kdatabase.net/k212763/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Vitreous Aspiration And Cutting, Ac-powered (HQE) |
| Date received | Aug 31, 2021 |
| Decision date | Aug 10, 2022 |
| Days to decision | 344 days |
| Third-party review | No |
| Combination product | No |
| PCCP authorized | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Visioncare Devices, LLC |
| Location | Anderson, CA, US |
| Contact | Rick Morgan |
| 510(k) history | 1 submissions · 1 cleared · 2022-2022 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k212763/> 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