

**K142510 UltraHealth Hybrid Contact Lens for Keratoconus,  
UltraHealth Flat Cornea Hybrid Contact Lens**Nov 19, 2014  
72 days to decisionK142510 · Product code: **HQD** · Ophthalmic  
Source: <https://www.510kdatabase.net/k142510/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)           |
| Submission type       | Traditional                                  |
| Device classification | Lens, Contact (other Material) - Daily (HQD) |
| Date received         | Sep 8, 2014                                  |
| Decision date         | Nov 19, 2014                                 |
| Days to decision      | 72 days                                      |
| Third-party review    | No   |
| Summary / Statement   | Summary                                      |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Synergeyes, Inc.</b>               |
| Location       | Rockville, MD, US                     |
| Contact        | Steven L. Ziemba                      |
| 510(k) history | 9 submissions · 9 cleared · 2006-2016 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k142510/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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