

**K100443 DEFINITIVE, FLEXLENS - SILICONE HYDROGEL**Oct 28, 2010  
253 days to decisionK100443 · Product code: **LPL** · Ophthalmic  
Source: <https://www.510kdatabase.net/k100443/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)     |
| Submission type       | Traditional                            |
| Device classification | Lenses, Soft Contact, Daily Wear (LPL) |
| Date received         | Feb 17, 2010                           |
| Decision date         | Oct 28, 2010                           |
| Days to decision      | 253 days                               |
| Third-party review    | No                                     |
| Summary / Statement   | Summary                                |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>X-Cel Contacts, Inc.</b>           |
| Location       | Grand Junction, CO, US                |
| Contact        | MARTIN DALSING                        |
| 510(k) history | 1 submissions · 1 cleared · 2010-2010 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100443/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 20, 2026