

**K110452 SOF-FORM II, UNILENS, UNISITE, SIMULVUE,  
AQUAFLEX, LL-38, BAYVUE AQUAFLEX MTO, UNILENS 38,  
UNISOFT, SIMULVUE 38 LLBI 2,**Apr 20, 2011  
63 days to decisionK110452 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k110452/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Feb 16, 2011
Decision date	Apr 20, 2011
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Unilens Corp., USA</b>
Location	Largo, FL, US
Contact	ALAN J FRAZER
510(k) history	14 submissions · 14 cleared · 1994-2014

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110452/> 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 6, 2026