FDA 510(k) Premarket Notification

CLEARED

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 decision

K110452 · Product code: **LPL** · Ophthalmic
Source: https://www.510kdatabase.net/k110452/

SUBMISSION DETAILS

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

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