

K122213 ENI-EYE SH SPHERE (EFROFILCON A) SOFT (HYDROPHILIC) CONTACT LENS FOR DAILY WEAR

Dec 12, 2012
140 days to decision

K122213 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k122213/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jul 25, 2012
Decision date	Dec 12, 2012
Days to decision	140 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Soflex Limited
Location	Greenwood Village, CO, US
Contact	Kevin Walls
510(k) history	3 submissions · 3 cleared · 2011-2013

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k122213/> 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 June 9, 2026