

**K122220 ENI-EYE SH SOFT K SEMI SCLERAL (EFROFILCON A)  
SOFT (HYDROPHILIC) KERATOCONUS AND IRREGULAR COR  
ENI-EYE SH SOFT K TORIC S**Mar 19, 2013  
237 days to decisionK122220 · Product code: LPL · Ophthalmic  
Source: <https://www.510kdatabase.net/k122220/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Jul 25, 2012
Decision date	Mar 19, 2013
Days to decision	237 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122220/> 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 9, 2026