

**K121201 SAVIE-AQUA 55UV (METHAFILCON A) TINNTED BLUE
SOFT (HYDROPHILIC) CONTACT LENS**

Oct 26, 2012
190 days to decision

K121201 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k121201/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Apr 19, 2012
Decision date	Oct 26, 2012
Days to decision	190 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	St. shine Optical Co., Ltd.
Location	Littleton, CO, US
Contact	ELLA LEE
510(k) history	11 submissions · 11 cleared · 2002-2026

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k121201/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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