

K153766 Clalen 54 (hioxifilcon D) Soft (hydrophilic) Contact Lens for Daily Wear, Clalen 58 (hioxifilcon A) Soft (hydrophilic) Contact Lens for Daily WearApr 8, 2016
100 days to decisionK153766 · Product code: LPL · Ophthalmic
Source: <https://www.510kdatabase.net/k153766/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Lenses, Soft Contact, Daily Wear (LPL)
Date received	Dec 30, 2015
Decision date	Apr 8, 2016
Days to decision	100 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	INTEROJO, Inc.
Location	Seoul, KR
Contact	Si-Chul Rho
510(k) history	3 submissions · 3 cleared · 2015-2022

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k153766/> 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 May 26, 2026