FDA 510(k) Premarket Notification

K041008 EYE-CEPT REWETTING DROPS

CLEARED

Jul 1, 2005
438 days to decision

K041008 · Product code: **LPN** · Ophthalmic
Source: https://www.510kdatabase.net/k041008/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Accessories, Soft Lens Products (LPN)
Date received	Apr 19, 2004
Decision date	Jul 1, 2005
Days to decision	438 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Optics Laboratory, Inc.**
Location	Shreveport, LA, US
Contact	J.R. CHEN
510(k) history	3 submissions · 3 cleared · 2005-2016

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k041008/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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