

K083184 TEARLAB OSMOLARITY SYSTEMMay 14, 2009
198 days to decisionK083184 · Product code: **OND** · Chemistry
Source: <https://www.510kdatabase.net/k083184/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Osmolality Of Tears (OND)
Date received	Oct 28, 2008
Decision date	May 14, 2009
Days to decision	198 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Ocusense, Inc.
Location	Philadelphia, PA, US
Contact	JANICE M HOGAN
510(k) history	1 submissions · 1 cleared · 2009-2009

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083184/> 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 23, 2026