

**K083316 3D OCT-1000 MARK II OPTICAL COHERENCE
TOMOGRAPHY SYSTEM**Mar 13, 2009
123 days to decisionK083316 · Product code: **OBO** · Ophthalmic
Source: <https://www.510kdatabase.net/k083316/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Nov 10, 2008
Decision date	Mar 13, 2009
Days to decision	123 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Topcon Medical Systems, Inc.
Location	Paramus, NJ, US
Contact	BARBARA S FANT
510(k) history	11 submissions · 11 cleared · 2003-2018

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k083316/> 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 19, 2026