FDA 510(k) Premarket Notification

K233561 3D Optical Coherence Tomography (3D OCT-1(type: Maestro2))

CLEARED

Apr 10, 2024
156 days to decision

K233561 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k233561/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Nov 6, 2023
Decision date	Apr 10, 2024
Days to decision	156 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Topcon Corporation**
Location	North Reading, MA, US
Contact	Ryota Kitawaki
Website	http://www.topcon.com
510(k) history	13 submissions · 13 cleared · 2014-2025

REGULATORY CONSULTANT

Consulting firm	**Orasi Consulting**
Contact	Lena Sattler

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov