FDA 510(k) Premarket Notification

K173707 P200TE

CLEARED

Feb 28, 2018
86 days to decision

K173707 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k173707/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tomography, Optical Coherence (OBO)
Date received	Dec 4, 2017
Decision date	Feb 28, 2018
Days to decision	86 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Optos Plc.**
Location	Washington, DC, US
Contact	Geoff Fatzinger
Website	http://www.optos.com/
510(k) history	15 submissions · 15 cleared · 1999-2024

Optos Plc. is a leading developer of ultra-widefield retinal imaging systems for eyecare professionals. The company specializes in innovative diagnostic devices that capture panoramic retinal images in a single shot. Now part of Nikon Corporation, Optos continues to operate as a distinct brand with a manufacturing facility in Washington, US. Optos has an established FDA 510(k) regulatory record with FDA 510(k) clearances from total submissions. All submissions focus on Ophthalmic devices. The company's first clearance was in 1999, with the most recent clearance in 2024, d...