FDA 510(k) Premarket Notification

# K190732 P200TxE

**CLEARED**

Jul 31, 2019
132 days to decision

K190732 · Product code: **OBO** · Ophthalmic
Source: https://www.510kdatabase.net/k190732/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Tomography, Optical Coherence (OBO) |
| Date received | Mar 21, 2019 |
| Decision date | Jul 31, 2019 |
| Days to decision | 132 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

| | |
|---|---|
| Company | **Optos Plc.** |
| Location | Washington, DC, US |
| Contact | Rachel Reay |
| 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...