

**K111628 P200T**Aug 19, 2011  
70 days to decisionK111628 · Product code: **MYC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k111628/>**SUBMISSION DETAILS**

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|                       |                                       |
|-----------------------|---------------------------------------|
| Decision              | Substantially Equivalent (Cleared)    |
| Submission type       | Special                               |
| Device classification | Ophthalmoscope, Laser, Scanning (MYC) |
| Date received         | Jun 10, 2011                          |
| Decision date         | Aug 19, 2011                          |
| Days to decision      | 70 days                               |
| Third-party review    | No                                    |
| Summary / Statement   | Summary                               |

**APPLICANT**

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|----------------|---|
| Company        | <b>Optos Plc.</b>   |
| Location       | Washington, DC, US  |
| Contact        | HOWARD M HOLSTEIN   |
| Website        | <a href="http://www.optos.com/">http://www.optos.com/</a> |
| 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...

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