

**K142897 P200DTx**Jan 16, 2015  
105 days to decisionK142897 · Product code: **MYC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k142897/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	Oct 3, 2014
Decision date	Jan 16, 2015
Days to decision	105 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Optos Plc.</b>
Location	Washington, DC, US
Contact	GUNHILD PAULSEN
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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