

**K060424 PANORAMIC, MODEL 200MA**Mar 17, 2006  
28 days to decisionK060424 · Product code: **MYC** · Ophthalmic  
Source: <https://www.510kdatabase.net/k060424/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	Feb 17, 2006
Decision date	Mar 17, 2006
Days to decision	28 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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