

K134039 DAYTONA ICG (P200TICG)Apr 11, 2014
101 days to decisionK134039 · Product code: **MYC** · Ophthalmic
Source: <https://www.510kdatabase.net/k134039/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	Dec 31, 2013
Decision date	Apr 11, 2014
Days to decision	101 days
Third-party review	No

APPLICANT

Company	Optos Plc.
Location	Washington, DC, US
Contact	RANDY PREBULA
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...