

K042001 PANORAMIC 200AOct 7, 2004
73 days to decisionK042001 · Product code: **HLI** · Ophthalmic
Source: <https://www.510kdatabase.net/k042001/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Jul 26, 2004
Decision date	Oct 7, 2004
Days to decision	73 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Optos Plc.
Location	Washington, DC, US
Contact	HOWARD M HOLSTEIN
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...
