

K192113 DRSpplusNov 15, 2019
102 days to decisionK192113 · Product code: **MYC** · Ophthalmic
Source: <https://www.510kdatabase.net/k192113/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	Aug 5, 2019
Decision date	Nov 15, 2019
Days to decision	102 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Centervue S.P.A.
Location	Padova, IT
Contact	Roberto Gabriotti
510(k) history	13 submissions · 13 cleared · 2010-2025

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