

K211328 EIDON FA, EIDON, EIDON AF, EIDON UWFLAug 19, 2021
108 days to decisionK211328 · Product code: **MYC** · Ophthalmic
Source: <https://www.510kdatabase.net/k211328/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Ophthalmoscope, Laser, Scanning (MYC)
Date received	May 3, 2021
Decision date	Aug 19, 2021
Days to decision	108 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

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

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