FDA 510(k) Premarket Notification

K133758 CENTERVUE MACULAR INTEGRITY ASSESSMENT

CLEARED

Apr 23, 2014
133 days to decision

K133758 · Product code: **HLI** · Ophthalmic
Source: https://www.510kdatabase.net/k133758/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Dec 11, 2013
Decision date	Apr 23, 2014
Days to decision	133 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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