FDA 510(k) Premarket Notification

CLEARED

K971671 HEIDELBERG RETINA ANGIOGRAPH FA/ICGA (HRA/C)

Jul 29, 1997
83 days to decision

K971671 · Product code: **HLI** · Ophthalmic
Source: https://www.510kdatabase.net/k971671/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	May 7, 1997
Decision date	Jul 29, 1997
Days to decision	83 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Heidelberg Engineering**
Location	Carlsbad, CA, US
Contact	GERHARD ZINSER
510(k) history	9 submissions · 9 cleared · 1991-2010