FDA 510(k) Premarket Notification

K822908 COHERENT FUNDUSL RETINAL CAMERA

CLEARED

Jan 5, 1983
97 days to decision

K822908 · Product code: **HKI** · Ophthalmic
Source: https://www.510kdatabase.net/k822908/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Camera, Ophthalmic, Ac-powered (HKI)
Date received	Sep 30, 1982
Decision date	Jan 5, 1983
Days to decision	97 days
Third-party review	No

APPLICANT

Company	**Coherent Medical Division**
Location	Mchenry, IL, US
510(k) history	6 submissions · 6 cleared · 1979-1990