FDA 510(k) Premarket Notification

K895010 MENTOR SPECTACLE BINOCULAR INDIRECT OPHTHALMOSCOPE

CLEARED

Sep 11, 1989
34 days to decision

K895010 · Product code: **HLI** · Ophthalmic
Source: https://www.510kdatabase.net/k895010/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Aug 8, 1989
Decision date	Sep 11, 1989
Days to decision	34 days
Third-party review	No

APPLICANT

Company	**Mentor O & O, Inc.**
Location	Mchenry, IL, US
Contact	MARK TOMA
510(k) history	18 submissions · 18 cleared · 1982-1996