FDA 510(k) Premarket Notification

K914484 LITESPOT(TM) LASER INDIRECT OPHTHALMOSCOPE

CLEARED

Jan 6, 1992
90 days to decision

K914484 · Product code: **HLI** · Ophthalmic
Source: https://www.510kdatabase.net/k914484/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Ac-powered (HLI)
Date received	Oct 8, 1991
Decision date	Jan 6, 1992
Days to decision	90 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Hgm Medical Laser Systems, Inc.**
Location	Salt Lake City, UT, US
Contact	GREGORY R MCARTHUR
510(k) history	18 submissions · 18 cleared · 1988-1992