FDA 510(k) Premarket Notification

K002044 MAGNA FORTIS OPHTHALMOSCOPE DIAGNOSTIC KIT

CLEARED

Sep 12, 2000
69 days to decision

K002044 · Product code: **HLJ** · Ophthalmic
Source: https://www.510kdatabase.net/k002044/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Ophthalmoscope, Battery-powered (HLJ)
Date received	Jul 5, 2000
Decision date	Sep 12, 2000
Days to decision	69 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Magna Fortis Corporation**
Location	Bellevue, WA, US
Contact	MARK WERBLUD
510(k) history	1 submissions · 1 cleared · 2000-2000