FDA 510(k) Premarket Notification

K873795 M-LENS (THIRTY DEGREE ENDOSCOPE)

CLEARED

Jan 14, 1988
119 days to decision

K873795 · Product code: **FEI** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k873795/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Instrument, Special Lens, For Endoscope (FEI)
Date received	Sep 17, 1987
Decision date	Jan 14, 1988
Days to decision	119 days
Third-party review	No

APPLICANT

Company	**Opto Vision, Inc.**
Location	Chicago, IL, US
Contact	HELMUT KREBS
510(k) history	2 submissions · 2 cleared · 1988-1989