FDA 510(k) Premarket Notification

K970875 ENDOLIGHT FIBEROPTIC ENDO-ILLUMINATOR (20 GA. & 19 GA.)

CLEARED

May 20, 1997
71 days to decision

K970875 · Product code: **MPA** · Ophthalmic
Source: https://www.510kdatabase.net/k970875/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoilluminator (MPA)
Date received	Mar 10, 1997
Decision date	May 20, 1997
Days to decision	71 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**American Medical Devices, Inc.**
Location	Atlanta, GA, US
Contact	FRANK J TIGHE
510(k) history	6 submissions · 6 cleared · 1997-1998