FDA 510(k) Premarket Notification

K863583 CHANGE IN FIBERLASE 100 ND:YAG MEDICAL LASER

CLEARED

Nov 24, 1986
76 days to decision

K863583 · Product code: **LNK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k863583/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser For Gastro-urology Use (LNK)
Date received	Sep 9, 1986
Decision date	Nov 24, 1986
Days to decision	76 days
Third-party review	No

APPLICANT

Company	**Laser Media**
Location	Hauppauge, NY, US
Contact	ROBERT A KAPLAN
510(k) history	12 submissions · 12 cleared · 1985-1987