FDA 510(k) Premarket Notification

K833499 FIBERLAS 100 MEDICAL SYSTEM

CLEARED

Apr 2, 1984
180 days to decision

K833499 · Product code: **LNK** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k833499/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Laser For Gastro-urology Use (LNK)
Date received	Oct 5, 1983
Decision date	Apr 2, 1984
Days to decision	180 days
Third-party review	No

APPLICANT

Company	**Fiberlase U.S.A.**
Location	7600 Ridge Blvd Brooklun, NY, US
510(k) history	1 submissions · 1 cleared · 1984-1984