FDA 510(k) Premarket Notification

K884379 MAGLINTE ENTEROCLYSIS CATHETER

CLEARED

Feb 28, 1989
133 days to decision

K884379 · Product code: **FGD** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k884379/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Retention, Barium Enema With Bag (FGD)
Date received	Oct 18, 1988
Decision date	Feb 28, 1989
Days to decision	133 days
Third-party review	No

APPLICANT

Company	**Lafayette Pharmacal, Inc.**
Location	Lafayette, IN, US
Contact	ROBERT A SHARP
510(k) history	4 submissions · 3 cleared · 1986-1993