FDA 510(k) Premarket Notification

K973844 GASTRIC AND RECTAL CATHETERS

CLEARED

Jun 4, 1999
604 days to decision

K973844 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k973844/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Oct 8, 1997
Decision date	Jun 4, 1999
Days to decision	604 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**G & J Electronics, Inc.**
Location	Toronto, Ontario, CA
Contact	SAM JUNDLER
510(k) history	2 submissions · 2 cleared · 1999-1999