FDA 510(k) Premarket Notification

K963064 ANO-RECTAL MANOMETRY OPTION, MODEL NUMBER UDS-ARM

CLEARED

Jun 5, 1997
302 days to decision

K963064 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k963064/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Aug 7, 1996
Decision date	Jun 5, 1997
Days to decision	302 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Laborie Medical Tech Corp.**
Location	Mississauga, CA
Contact	THOMAS HIRTE
510(k) history	5 submissions · 5 cleared · 1995-1999