FDA 510(k) Premarket Notification

K991389 ANORECTAL MANOMETRY SUITE, MODEL 9032S0201

CLEARED

Jul 15, 1999
85 days to decision

K991389 · Product code: **FFX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k991389/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Apr 21, 1999
Decision date	Jul 15, 1999
Days to decision	85 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Medtronic Functional Diagnostics A/S**
Location	Skovlunde, DK
Contact	ANN-CHRISTINE JONSSON
510(k) history	11 submissions · 11 cleared · 1999-2002