

K991389 ANORECTAL MANOMETRY SUITE, MODEL 9032S0201Jul 15, 1999
85 days to decisionK991389 · 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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k991389/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 14, 2026