

**K000386 POLYGRAM 98 ANORECTAL FUNCTION TESTING
APPLICATION, MODEL 9043S0111**May 5, 2000
88 days to decisionK000386 · Product code: FFX · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k000386/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Feb 7, 2000
Decision date	May 5, 2000
Days to decision	88 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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