

K011472 POLYGRAM 98 ANORECTAL FUNCTION TESTING APPLICATION, POLYGRAM 98 ESOPHAGEAL MANOMETRY APPLICATION, POLYGRAF ID

Aug 10, 2001
88 days to decision

K011472 · Product code: **FFX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011472/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	May 14, 2001
Decision date	Aug 10, 2001
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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Device record: <https://www.510kdatabase.net/k011472/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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