

**K010130 POLYGRAM 98 ESOPHAGEAL MANOMETRY TESTING
APPLICATION, MODEL 9043S0103**Feb 7, 2001
22 days to decisionK010130 · Product code: FFX · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k010130/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jan 16, 2001
Decision date	Feb 7, 2001
Days to decision	22 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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