

K011471 BILITEC 2000, POLYGRAM '98 PH TESTING APPLICATION (INCL.BILE), OPTICAL FIBER PROBERNov 8, 2002
543 days to decisionK011471 · Product code: FFX · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k011471/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	May 14, 2001
Decision date	Nov 8, 2002
Days to decision	543 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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