

**K981733 DIGITRAPPER DELTA, MODEL 9043G0201 AND
POLYGRAM '98 PH EXTENSION MODEL 9043S0111**Feb 4, 1999
262 days to decisionK981733 · Product code: FFX · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k981733/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	May 18, 1998
Decision date	Feb 4, 1999
Days to decision	262 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/k981733/> 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