

K980946 MARK II CO2 FLUSH MANOMETRIC PERFUSION PUMP & MARK II MANOMETRIC PERFUSION PUMPJun 8, 1998
87 days to decisionK980946 · Product code: FFX · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k980946/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Mar 13, 1998
Decision date	Jun 8, 1998
Days to decision	87 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Dentsleeve Pty., Ltd.
Location	Golden, CO, US
Contact	MARCUS TIPPETT
510(k) history	3 submissions · 3 cleared · 1998-2001

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