

**K013154 MARK II/MARK III MANOMETRIC PERFUSION PUMP**Oct 19, 2001  
29 days to decisionK013154 · Product code: **FFX** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k013154/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Sep 20, 2001
Decision date	Oct 19, 2001
Days to decision	29 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Dentsleeve Pty., Ltd.</b>
Location	Golden, CO, US
Contact	ROBERT N CLARK
510(k) history	3 submissions · 3 cleared · 1998-2001

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k013154/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 30, 2026