

K122294 PRESSURIZED INFUSION PUMPNov 1, 2012
93 days to decisionK122294 · Product code: **FFX** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k122294/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Gastrointestinal Motility (electrical) (FFX)
Date received	Jul 31, 2012
Decision date	Nov 1, 2012
Days to decision	93 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Mui Scientific
Location	Mississauga, Ontario, CA
Contact	TAMMY MUI
510(k) history	4 submissions · 4 cleared · 1983-2017

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k122294/> 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 June 1, 2026