

**K922562 STIMTECH PFX, CATALOG NUMBER 78-8540**Oct 13, 1993  
499 days to decisionK922562 · Product code: **KPI** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k922562/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stimulator, Electrical, Non-implantable, For Incontinence (KPI)
Date received	Jun 1, 1992
Decision date	Oct 13, 1993
Days to decision	499 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Stimtech Products</b>
Location	Southbridge, MA, US
Contact	JAMES WASON
510(k) history	3 submissions · 3 cleared · 1989-1993

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922562/> 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