

**K922398 4 SURE TM ENEMA BAG SET**Jun 17, 1993  
392 days to decisionK922398 · Product code: **FCE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k922398/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Enema Kit (FCE)
Date received	May 21, 1992
Decision date	Jun 17, 1993
Days to decision	392 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

---

Company	<b>Boston Pacific Medical, Inc.</b>
Location	Boston, MA, US
Contact	RICHARD A DEROSA
510(k) history	11 submissions · 8 cleared · 1992-1994

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k922398/> 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 May 26, 2026