

K922401 4 SURE TM COLOSTOMY POUCHJun 10, 1992
20 days to decisionK922401 · Product code: **EZQ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k922401/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pouch, Colostomy (EZQ) |
| Date received | May 21, 1992 |
| Decision date | Jun 10, 1992 |
| Days to decision | 20 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|--|
| Company | Boston Pacific Medical, Inc. |
| Location | Boston, MA, US |
| Contact | RANDALL GREEN |
| 510(k) history | 11 submissions · 8 cleared · 1992-1994 |

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