FDA 510(k) Premarket Notification

# K994272 AUTOMATED CORE BIOPSY DEVICE

**CLEARED**

Jan 7, 2000
18 days to decision

K994272 · Product code: **KNW** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k994272/

## SUBMISSION DETAILS

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|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Biopsy (KNW) |
| Date received | Dec 20, 1999 |
| Decision date | Jan 7, 2000 |
| Days to decision | 18 days |
| Third-party review | No |
| Summary / Statement | Statement |

## APPLICANT

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|---|---|
| Company | **Promex, Inc.** |
| Location | Indianapolis, IN, US |
| Contact | JOSEPH L MARK |
| 510(k) history | 18 submissions · 18 cleared · 1994-2002 |