

K011270 AUTOMATED CORE BIOPSY DEVICEJun 22, 2001
57 days to decisionK011270 · Product code: **FCG** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k011270/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Biopsy Needle (FCG) |
| Date received | Apr 26, 2001 |
| Decision date | Jun 22, 2001 |
| Days to decision | 57 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k011270/> 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 May 20, 2026