

**K954265 TROCAR STYLE NEEDLE/CO-AXIAL INTRODUCER
NEEDLE**Sep 29, 1995
17 days to decisionK954265 · Product code: **KNW** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k954265/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Biopsy (KNW) |
| Date received | Sep 12, 1995 |
| Decision date | Sep 29, 1995 |
| Days to decision | 17 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/k954265/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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