

K953880 BIOPSY NEEDLESep 8, 1995
21 days to decisionK953880 · Product code: **KNW** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k953880/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Biopsy (KNW) |
| Date received | Aug 18, 1995 |
| Decision date | Sep 8, 1995 |
| Days to decision | 21 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Biopsys Medical, Inc. |
| Location | San Juan Capistrano, CA, US |
| Contact | MARK A COLE |
| 510(k) history | 15 submissions · 15 cleared · 1994-1997 |

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