

**K943863 NEEDLE GUIDE**Dec 29, 1994  
143 days to decisionK943863 · Product code: **IYN** · Radiology  
Source: <https://www.510kdatabase.net/k943863/>**SUBMISSION DETAILS**

---

|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | System, Imaging, Pulsed Doppler, Ultrasonic (IYN) |
| Date received         | Aug 8, 1994                                       |
| Decision date         | Dec 29, 1994                                      |
| Days to decision      | 143 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

---

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

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943863/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 20, 2026