

K912088 BIOPSY ACCESSORIES FOR ULTRASOUND PROBESDec 5, 1991
206 days to decisionK912088 · Product code: **ITX** · Radiology
Source: <https://www.510kdatabase.net/k912088/>**SUBMISSION DETAILS**

| | |
|-----------------------|--|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Transducer, Ultrasonic, Diagnostic (ITX) |
| Date received | May 13, 1991 |
| Decision date | Dec 5, 1991 |
| Days to decision | 206 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Biosound, Inc. |
| Location | Indianapolis, IN, US |
| Contact | CARRI STICHNOTH |
| 510(k) history | 39 submissions · 39 cleared · 1983-1997 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k912088/> 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