

**K883238 GENESIS II TRANSCRANIAL PROBE**Aug 24, 1988  
23 days to decisionK883238 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k883238/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received         | Aug 1, 1988                                    |
| Decision date         | Aug 24, 1988                                   |
| Days to decision      | 23 days  |
| Third-party review    | No   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Biosound, Inc.</b>                   |
| Location       | Indianapolis, IN, US                    |
| Contact        | ROBERT COURTNEY                         |
| 510(k) history | 39 submissions · 39 cleared · 1983-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k883238/>; 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