

**K020068 SONOREAL 3D SYSTEM**Mar 4, 2002  
54 days to decisionK020068 · Product code: **IYO** · Radiology  
Source: <https://www.510kdatabase.net/k020068/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)             |
| Submission type       | Traditional                                    |
| Device classification | System, Imaging, Pulsed Echo, Ultrasonic (IYO) |
| Date received         | Jan 9, 2002                                    |
| Decision date         | Mar 4, 2002                                    |
| Days to decision      | 54 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Bio Medi Com</b>                   |
| Location       | Indianapolis, IN, US                  |
| Contact        | COLLEEN DENSMORE                      |
| 510(k) history | 3 submissions · 3 cleared · 2001-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k020068/> 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 19, 2026