

**K000976 DIAMOND (MAMMOGRAPHIC X-RAY SYSTEM)**Jun 1, 2000  
66 days to decisionK000976 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k000976/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Mammographic (IZH)  |
| Date received         | Mar 27, 2000                       |
| Decision date         | Jun 1, 2000                        |
| Days to decision      | 66 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---|
| Company        | <b>Instrumentarium Imaging, Inc.</b>    |
| Location       | Milwaukee, WI, US                       |
| Contact        | MAX LINDERT                             |
| 510(k) history | 24 submissions · 24 cleared · 1989-2000 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k000976/> 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