

**K953248 IRIS BILATERAL TMJ**Oct 23, 1995  
104 days to decisionK953248 · Product code: **LNH** · Radiology  
Source: <https://www.510kdatabase.net/k953248/>**SUBMISSION DETAILS**

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|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)               |
| Submission type       | Traditional                                      |
| Device classification | System, Nuclear Magnetic Resonance Imaging (LNH) |
| Date received         | Jul 11, 1995                                     |
| Decision date         | Oct 23, 1995                                     |
| Days to decision      | 104 days   |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|--|
| Company        | <b>Hitachi Medical Systems America, Inc.</b> |
| Location       | Twinsburg, OH, US                            |
| Contact        | JAMES JOCHEN ROGERS                          |
| 510(k) history | 100 submissions · 100 cleared · 1991-2017    |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k953248/> 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 16, 2026