

**K950608 DIGITAL SPOT MAMMOGRAPHY FOR STEROTACTIC APPLICATION**Mar 2, 1995  
21 days to decisionK950608 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k950608/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Mammographic (IZH)  |
| Date received         | Feb 9, 1995                        |
| Decision date         | Mar 2, 1995                        |
| Days to decision      | 21 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Lorad Corp.</b>                      |
| Location       | Danbury, CT, US                         |
| Contact        | MARVIN ROSENBAUM                        |
| 510(k) history | 12 submissions · 12 cleared · 1994-1999 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k950608/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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