

**K904517 MAMMOSPOT 3 AND MAMMOSPOT 8**Nov 15, 1990  
43 days to decisionK904517 · Product code: **IZH** · Radiology  
Source: <https://www.510kdatabase.net/k904517/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, X-ray, Mammographic (IZH)  |
| Date received         | Oct 3, 1990                        |
| Decision date         | Nov 15, 1990                       |
| Days to decision      | 43 days                            |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>American Mammographics, Inc.</b>   |
| Location       | Chattanooga, TN, US                   |
| Contact        | GORDON HIXSON                         |
| 510(k) history | 4 submissions · 4 cleared · 1990-2002 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k904517/>, 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