

**K031206 RADIOMED SOFT TISSUE MARKER**May 21, 2003  
35 days to decisionK031206 · Product code: **JAK** · Radiology  
Source: <https://www.510kdatabase.net/k031206/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)        |
| Submission type       | Special                                   |
| Device classification | System, X-ray, Tomography, Computed (JAK) |
| Date received         | Apr 16, 2003                              |
| Decision date         | May 21, 2003                              |
| Days to decision      | 35 days                                   |
| Third-party review    | No  |
| Summary / Statement   | Summary                                   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Radiomed Corp.</b>                 |
| Location       | Billerica, MA, US                     |
| Contact        | GORDON ROBERTS                        |
| 510(k) history | 2 submissions · 2 cleared · 2000-2003 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k031206/> 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