

**K963789 DTX-100 BONE DENSITOMETER**Jul 14, 1997  
297 days to decisionK963789 · Product code: **KGI** · Radiology  
Source: <https://www.510kdatabase.net/k963789/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Densitometer, Bone (KGI)           |
| Date received         | Sep 20, 1996                       |
| Decision date         | Jul 14, 1997                       |
| Days to decision      | 297 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Osteometer Meditech A/S</b>        |
| Location       | Dallas, TX, US                        |
| Contact        | BERT HUDSON                           |
| 510(k) history | 2 submissions · 2 cleared · 1997-1997 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k963789/> 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 20, 2026