

**K040911 VITALHEAT**Jun 22, 2004  
75 days to decisionK040911 · Product code: **DWJ** · Cardiovascular  
Source: <https://www.510kdatabase.net/k040911/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | System, Thermal Regulating (DWJ)   |
| Date received         | Apr 8, 2004                        |
| Decision date         | Jun 22, 2004                       |
| Days to decision      | 75 days                            |
| Third-party review    | Yes                                |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Dynatherm Medical, Inc.</b>        |
| Location       | Burlingame, CA, US                    |
| Contact        | JOHN R KANE                           |
| 510(k) history | 1 submissions · 1 cleared · 2004-2004 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k040911/> 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 July 3, 2026