

**K083437 MODIFICATION TO T2 RECON NAIL SYSTEM**Dec 18, 2008  
28 days to decisionK083437 · Product code: **HSB** · Orthopedic  
Source: <https://www.510kdatabase.net/k083437/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                  |
| Submission type       | Special   |
| Device classification | Rod, Fixation, Intramedullary And Accessories (HSB) |
| Date received         | Nov 20, 2008  |
| Decision date         | Dec 18, 2008  |
| Days to decision      | 28 days   |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---|
| Company        | <b>Howmedica Osteonics Corp.</b>          |
| Location       | Allendale, NJ, US                         |
| Contact        | AVITAL MERL-MARGULIES                     |
| 510(k) history | 288 submissions · 288 cleared · 1999-2020 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k083437/> 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 15, 2026