

**K110259 ARCHITEX SPACE MAINTENANCE SYSTEM**Apr 13, 2011  
75 days to decisionK110259 · Product code: **JEY** · DentalSource: <https://www.510kdatabase.net/k110259/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Plate, Bone (JEY)                  |
| Date received         | Jan 28, 2011                       |
| Decision date         | Apr 13, 2011                       |
| Days to decision      | 75 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Medtronic Sofamor Danek USA, Inc.</b>  |
| Location       | Memphis, TN, US                           |
| Contact        | KELLY DAVIDSON                            |
| 510(k) history | 170 submissions · 159 cleared · 2000-2026 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k110259/> 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 17, 2026