

**K093943 BIOSURE SYNC TIBIAL FIXATION DEVICE, 6MM,  
8MM,10MM,12MM**Mar 5, 2010  
73 days to decisionK093943 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k093943/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received         | Dec 22, 2009   |
| Decision date         | Mar 5, 2010  |
| Days to decision      | 73 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|--|
| Company        | <b>Smith &amp; Nephew Inc., Endoscopy Div.</b> |
| Location       | Andover, MA, US                                |
| Contact        | JULIE ACKER                                    |
| 510(k) history | 10 submissions · 10 cleared · 2007-2024        |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k093943/>; 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 26, 2026