

**K160500 Elite SPK, Compasso, Elite SPK Kit**Apr 20, 2016  
57 days to decisionK160500 · Product code: **MBI** · Orthopedic  
Source: <https://www.510kdatabase.net/k160500/>**SUBMISSION DETAILS**

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|                       |  |
|-----------------------|--|
| Decision              | Substantially Equivalent (Cleared)                   |
| Submission type       | Traditional  |
| Device classification | Fastener, Fixation, Nondegradable, Soft Tissue (MBI) |
| Date received         | Feb 23, 2016   |
| Decision date         | Apr 20, 2016   |
| Days to decision      | 57 days  |
| Third-party review    | No   |
| Summary / Statement   | Summary  |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Ncs Lab Srl</b>                    |
| Location       | Carpi, IT                             |
| Contact        | Matteo Mantovani                      |
| 510(k) history | 4 submissions · 4 cleared · 2012-2022 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k160500/> 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