

**K052011 PILONPLATE WITH ANGULAR STABILITY**Aug 10, 2005  
16 days to decisionK052011 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k052011/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Plate, Fixation, Bone (HRS)        |
| Date received         | Jul 25, 2005                       |
| Decision date         | Aug 10, 2005                       |
| Days to decision      | 16 days                            |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|--|
| Company        | <b>I.T.S. Implantat-Technologie-Systeme GmbH</b> |
| Location       | Prior Lake, MN, US                               |
| Contact        | AL LIPPINCOTT                                    |
| 510(k) history | 13 submissions · 13 cleared · 2004-2010          |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k052011/> 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 18, 2026