

**K100373 TYCHE PEDICLE SCREW SYSTEM**Jun 30, 2010  
138 days to decisionK100373 · Product code: **MNH** · Orthopedic  
Source: <https://www.510kdatabase.net/k100373/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)                |
| Submission type       | Traditional                                       |
| Device classification | Orthosis, Spondylolisthesis Spinal Fixation (MNH) |
| Date received         | Feb 12, 2010                                      |
| Decision date         | Jun 30, 2010                                      |
| Days to decision      | 138 days  |
| Third-party review    | No  |
| Summary / Statement   | Summary   |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Kyung Won Medical Co., Ltd.</b>    |
| Location       | Santa Fe Springs, CA, US              |
| Contact        | JOYCE BANG                            |
| 510(k) history | 4 submissions · 4 cleared · 2007-2010 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k100373/> 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