

**K033303 WAFER SYSTEM**Jun 24, 2004  
254 days to decisionK033303 · Product code: **HRS** · Orthopedic  
Source: <https://www.510kdatabase.net/k033303/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Plate, Fixation, Bone (HRS)        |
| Date received         | Oct 14, 2003                       |
| Decision date         | Jun 24, 2004                       |
| Days to decision      | 254 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---|
| Company        | <b>Spine Wave, Inc.</b>                 |
| Location       | Shelton, CT, US                         |
| Contact        | RONALD K SMITH                          |
| 510(k) history | 57 submissions · 57 cleared · 2004-2025 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k033303/> 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 20, 2026