

**K943666 ENVISION ARTHROSCOPY VISUALIZATION SYSTEM**Nov 17, 1994  
112 days to decisionK943666 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k943666/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Arthroscope (HRX)                  |
| Date received         | Jul 28, 1994                       |
| Decision date         | Nov 17, 1994                       |
| Days to decision      | 112 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Envision Surgical System, Inc.</b> |
| Location       | Palo Alto, CA, US                     |
| Contact        | ROBERT KOTMEL                         |
| 510(k) history | 3 submissions · 3 cleared · 1994-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943666/> 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 22, 2026