

**K943628 ARTHROSCOPE**Nov 22, 1994  
119 days to decisionK943628 · Product code: **HRX** · Orthopedic  
Source: <https://www.510kdatabase.net/k943628/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Arthroscope (HRX)                  |
| Date received         | Jul 26, 1994                       |
| Decision date         | Nov 22, 1994                       |
| Days to decision      | 119 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Statement                          |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Electro Fiberoptics Corp.</b>      |
| Location       | Northborough, MA, US                  |
| Contact        | KENNETH J DURBIN                      |
| 510(k) history | 3 submissions · 3 cleared · 1993-1994 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k943628/> 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 21, 2026