

**K910734 MEDISYSTEMS HEMODIALYSIS FISTULA SET**Jun 20, 1991  
119 days to decisionK910734 · Product code: **FIE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k910734/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Needle, Fistula (FIE)              |
| Date received         | Feb 21, 1991                       |
| Decision date         | Jun 20, 1991                       |
| Days to decision      | 119 days                           |
| Third-party review    | No                                 |

**APPLICANT**

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|----------------|---|
| Company        | <b>Medisystems Corp.</b>                |
| Location       | Mchenry, IL, US                         |
| Contact        | ALAN C HINTON                           |
| 510(k) history | 22 submissions · 22 cleared · 1981-2007 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k910734/>; 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 June 29, 2026