

K902564 NEEDLE, DIALYSISMar 1, 1991
263 days to decisionK902564 · Product code: **FIE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k902564/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Needle, Fistula (FIE) |
| Date received | Jun 11, 1990 |
| Decision date | Mar 1, 1991 |
| Days to decision | 263 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Gainor Medical Europe, Ltd. |
| Location | Mcdonough, GA, US |
| Contact | MARK GAINOR |
| 510(k) history | 13 submissions · 13 cleared · 1990-1994 |

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