

K901179 ENEMA BUCKET SETJun 28, 1990
107 days to decisionK901179 · Product code: **FCE** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k901179/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------|
| Decision | Substantially Equivalent - K |
| Submission type | Traditional |
| Device classification | Enema Kit (FCE) |
| Date received | Mar 13, 1990 |
| Decision date | Jun 28, 1990 |
| Days to decision | 107 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Orion Life Systems, Inc. |
| Location | Wheeling, IL, US |
| Contact | JOHN L LAEMMAR |
| 510(k) history | 33 submissions · 16 cleared · 1990-1995 |

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