

K913721 FST CATH - UI USRODYNAMIC CATH INTRODUCER SYSTEMOct 8, 1991
49 days to decisionK913721 · Product code: **FEN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k913721/>**SUBMISSION DETAILS**

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|-----------------------|--------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Device, Cystometric, Hydraulic (FEN) |
| Date received | Aug 20, 1991 |
| Decision date | Oct 8, 1991 |
| Days to decision | 49 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---|
| Company | Fiberoptic Sensor Technologies, Inc. |
| Location | Plymouth, MI, US |
| Contact | DOUGLAS G TOMASKO |
| 510(k) history | 11 submissions · 11 cleared · 1987-1995 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k913721/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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