

K771725 BIOSP. TOTAL OSSICULAR REPLACE. PROSTHE.Sep 26, 1977
13 days to decisionK771725 · Product code: **FEX** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k771725/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Instrument, Catheter, Punch (FEX) |
| Date received | Sep 13, 1977 |
| Decision date | Sep 26, 1977 |
| Days to decision | 13 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Xomed, Inc. |
| Location | Arnold, MO, US |
| 510(k) history | 82 submissions · 81 cleared · 1976-2000 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k771725/> Data sourced from FDA 510(k) public records (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. - Generated May 21, 2026