

K161672 SpeediCath Flex CoudeSep 29, 2016
112 days to decisionK161672 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k161672/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Urethral (GBM) |
| Date received | Jun 9, 2016 |
| Decision date | Sep 29, 2016 |
| Days to decision | 112 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Coloplast Corp. |
| Location | Marietta, GA, US |
| Contact | Rebecca S. Roberts |
| 510(k) history | 54 submissions · 47 cleared · 1985-2025 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k161672/> 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 June 2, 2026