

K181206 GentleCath Glide Intermittent Urinary CatheterAug 16, 2018
101 days to decisionK181206 · Product code: **GBM** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k181206/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Urethral (GBM) |
| Date received | May 7, 2018 |
| Decision date | Aug 16, 2018 |
| Days to decision | 101 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Convatec Limited |
| Location | Deeside, GB |
| Contact | Elinor Jones |
| Website | https://www.convatec.com/ |
| 510(k) history | 10 submissions · 9 cleared · 2016-2026 |

Convatec Limited is a global medical device manufacturer specializing in chronic disease management solutions. The company operates with a manufacturing facility in Deeside, United Kingdom, and serves patients and healthcare professionals worldwide through innovative product portfolios. Convatec has received FDA 510(k) clearances from total submissions since 2016. The company's cleared devices span Gastroenterology & Urology and General & Plastic Surgery categories, with a strong focus on intermittent urinary catheters, fecal management systems, and advanced wound care dr...
