

K172924 GentleCath Intermittent Urinary CatheterNov 21, 2017
57 days to decisionK172924 · Product code: **KOD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k172924/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catheter, Urological (KOD) |
| Date received | Sep 25, 2017 |
| Decision date | Nov 21, 2017 |
| Days to decision | 57 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Convatec Limited |
| Location | Deeside, GB |
| Contact | Hannah Sharp |
| 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...
