

**K161344 GentleCath Glide Intermittent Catheter**Sep 20, 2016  
130 days to decisionK161344 · Product code: **KOD** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k161344/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urological (KOD)
Date received	May 13, 2016
Decision date	Sep 20, 2016
Days to decision	130 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Convatec Limited</b>
Location	Deeside, GB
Contact	ELINOR JONES
Website	<a href="https://www.convatec.com/">https://www.convatec.com/</a>
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...

---