

## K213283 GentleCath Air for Men Hydrophilic Intermittent Urinary Catheter

Jun 22, 2022  
264 days to decisionK213283 · Product code: **GBM** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k213283/>

### SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Urethral (GBM)
Date received	Oct 1, 2021
Decision date	Jun 22, 2022
Days to decision	264 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

### APPLICANT

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Company	<b>Convatec Limited</b>
Location	Deeside, GB
Contact	Louise Hollywood
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...