

K252943 GentleCath Air for MenApr 1, 2026
198 days to decisionK252943 · Product code: **EZD** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k252943/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Sep 15, 2025
Decision date	Apr 1, 2026
Days to decision	198 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GentleCath Glide Intermittent Catheter; GentleCath Air for Women

APPLICANT

Company	Convatec Limited
Location	Deeside, GB
Contact	Danielle Gibboney
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...