

K232665 GentleCath Air for Women (CH10)Jan 25, 2024
147 days to decisionK232665 · Product code: **EZD** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k232665/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Straight (EZD)
Date received	Aug 31, 2023
Decision date	Jan 25, 2024
Days to decision	147 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary
Other names	GentleCath Air for Women (CH12); GentleCath Air for Women (CH14)

APPLICANT

Company	Convatec
Location	Skillman, NJ, US
Contact	Kim Jones
510(k) history	7 submissions · 7 cleared · 2008-2025

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