

K173675 AQUACEL Ag+ EXTRA Enhanced Hydrofiber Dressing with Silver and Strengthening FiberJul 20, 2018
232 days to decisionK173675 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k173675/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 30, 2017
Decision date	Jul 20, 2018
Days to decision	232 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Convatec Limited
Location	Deeside, GB
Contact	Justin Lovelace
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...

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Device record: <https://www.510kdatabase.net/k173675/>. Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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