

K152926 AQUACEL Ag Surgical SP DressingJan 21, 2016
108 days to decisionK152926 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k152926/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Oct 5, 2015 |
| Decision date | Jan 21, 2016 |
| Days to decision | 108 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Convatec Limited |
| Location | Deeside, GB |
| Contact | AARON SIBLEY |
| 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...
