

K121275 AQUACEL AG EXTRA HYDROFIBER DRESSING WITH SILVER AND STRENGTHENING FIBERJul 25, 2012
89 days to decisionK121275 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k121275/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Apr 27, 2012 |
| Decision date | Jul 25, 2012 |
| Days to decision | 89 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Convatec, Inc. |
| Location | Skillman, NJ, US |
| Contact | KATRINA FIEDLER |
| 510(k) history | 7 submissions · 6 cleared · 2010-2023 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k121275/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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