

K091034 AQUACEL AG SURGICALDec 16, 2009
250 days to decisionK091034 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k091034/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Apr 10, 2009 |
| Decision date | Dec 16, 2009 |
| Days to decision | 250 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k091034/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated May 26, 2026