

K111365 VITALA CONTINENCE CONTROL DEVICEAug 19, 2011
95 days to decisionK111365 · Product code: **EZQ** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k111365/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Pouch, Colostomy (EZQ) |
| Date received | May 16, 2011 |
| Decision date | Aug 19, 2011 |
| Days to decision | 95 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k111365/> 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