

K092348 POLY FIT HIGH HYDRATING ANTIMICROBIAL DRESSINGSApr 8, 2010
247 days to decisionK092348 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k092348/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Aug 4, 2009 |
| Decision date | Apr 8, 2010 |
| Days to decision | 247 days |
| Third-party review | No |
| Summary / Statement | Statement |

APPLICANT

| | |
|----------------|---------------------------------------|
| Company | Polyremedy, Inc. |
| Location | Laguna Niguel, CA, US |
| Contact | GARY MOCNIK |
| 510(k) history | 3 submissions · 3 cleared · 2010-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k092348/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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