

**K122595 HYDROPERMEATE TOPICAL EMULSION,  
ANSWER2SKIN SUNBURN RELIEF CREAM, ANSWER2SKIN  
FIRST AID CREAM**May 1, 2013  
250 days to decisionK122595 · Product code: **FRO** · General & Plastic Surgery  
Source: <https://www.510kdatabase.net/k122595/>**SUBMISSION DETAILS**

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|                       |                                    |
|-----------------------|------------------------------------|
| Decision              | Substantially Equivalent (Cleared) |
| Submission type       | Traditional                        |
| Device classification | Dressing, Wound, Drug (FRO)        |
| Date received         | Aug 24, 2012                       |
| Decision date         | May 1, 2013                        |
| Days to decision      | 250 days                           |
| Third-party review    | No                                 |
| Summary / Statement   | Summary                            |

**APPLICANT**

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|----------------|---------------------------------------|
| Company        | <b>Dermal Life, LLC</b>               |
| Location       | Fairfax, VA, US                       |
| Contact        | DIANE HORWITZ, PH.D., RAC             |
| 510(k) history | 1 submissions · 1 cleared · 2013-2013 |

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k122595/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 9, 2026