

K110727 HYLATOPICPLUS CREAMApr 1, 2011
16 days to decisionK110727 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k110727/>**SUBMISSION DETAILS**

| | |
|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Special |
| Device classification | Dressing, Wound, Drug (FRO) |
| Date received | Mar 16, 2011 |
| Decision date | Apr 1, 2011 |
| Days to decision | 16 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Precision Dermatology Incorporated |
| Location | Cumberland, RI, US |
| Contact | RONALD M GURGE |
| 510(k) history | 3 submissions · 3 cleared · 2011-2012 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k110727/> 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 June 9, 2026