

K143058 PuraDerm GelFeb 13, 2015
112 days to decisionK143058 · Product code: **FRO** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k143058/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Oct 24, 2014
Decision date	Feb 13, 2015
Days to decision	112 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	3-D Matrix, Inc.
Location	Waltham, MA, US
Contact	Lisa Spirio
510(k) history	7 submissions · 7 cleared · 2015-2023

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