

K193085 PuraDERM GelMay 11, 2020
188 days to decisionK193085 · Product code: **FRO** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k193085/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dressing, Wound, Drug (FRO)
Date received	Nov 5, 2019
Decision date	May 11, 2020
Days to decision	188 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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