

**K210211 PuraStat-OM**Oct 8, 2021  
254 days to decisionK210211 · Product code: **OLR** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k210211/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Oral Wound Dressing (OLR)
Date received	Jan 27, 2021
Decision date	Oct 8, 2021
Days to decision	254 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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

**REGULATORY CONSULTANT**

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Consulting firm	<b>Streamline Regulatory</b>
Contact	Stephen P. Rhodes

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

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