

**K242634 PuraStat**Jan 15, 2025  
134 days to decisionK242634 · Product code: **PHN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k242634/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Protective Coating, Mucoadhesive Application, For The Rectal Mucosa (PHN)
Date received	Sep 3, 2024
Decision date	Jan 15, 2025
Days to decision	134 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>3-D Matrix Europe SAS</b>
Location	Caluire Et Cuire, FR
Contact	Audrey Vion
510(k) history	4 submissions · 4 cleared · 2024-2026

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k242634/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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