

**K253923 PuraStat**Jan 7, 2026  
30 days to decisionK253923 · Product code: **PHN** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k253923/>**SUBMISSION DETAILS**

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|                       |   |
|-----------------------|---|
| Decision              | Substantially Equivalent (Cleared)  |
| Submission type       | Special   |
| Device classification | Protective Coating, Mucoadhesive Application, For The Rectal Mucosa (PHN) |
| Date received         | Dec 8, 2025   |
| Decision date         | Jan 7, 2026   |
| Days to decision      | 30 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/k253923/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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