

K213552 PuraStat-RMApr 1, 2022
144 days to decisionK213552 · Product code: **PHN** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k213552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Protective Coating, Mucoadhesive Application, For The Rectal Mucosa (PHN)
Date received	Nov 8, 2021
Decision date	Apr 1, 2022
Days to decision	144 days
Third-party review	No
Combination product	No
PCCP authorized	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

REGULATORY CONSULTANT

Consulting firm	Streamline Regulatory
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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