

**K222481 PuraStat**Feb 28, 2023  
195 days to decisionK222481 · Product code: **QAU** · General & Plastic SurgerySource: <https://www.510kdatabase.net/k222481/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Device For Endoscopic Gastrointestinal Use (QAU)
Date received	Aug 17, 2022
Decision date	Feb 28, 2023
Days to decision	195 days
Third-party review	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

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k222481/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026