

K210098 PuraStat-GIJun 25, 2021
162 days to decisionK210098 · Product code: **QAU** · General & Plastic Surgery
Source: <https://www.510kdatabase.net/k210098/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Hemostatic Device For Endoscopic Gastrointestinal Use (QAU)
Date received	Jan 14, 2021
Decision date	Jun 25, 2021
Days to decision	162 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

CLINICAL EVIDENCE - NCT02833558**Purastat® vs Standard Therapy for Haemostasis During Endoscopic Submucosal Dissection**

Status	Completed - <i>No results published to ClinicalTrials.gov</i>
Enrollment	101 patients (actual)
Study sites	1 site
Condition studied	Gastrointestinal Haemorrhage
Primary purpose	Treatment
Study type	Interventional
Study design	Parallel
Masking	Single blind
Completion date	May 18, 2018
Sponsor	Portsmouth Hospitals NHS Trust (Other_gov)

Primary outcome

The number of times intraprocedural heat therapy is used to achieve haemostasis in ESD in both the PuraStat® and control arms of the study

Secondary outcome

The length of the procedure in the PuraStat® and control arm of the study

Source: ClinicalTrials.gov / U.S. National Library of Medicine - clinicaltrials.gov/study/NCT02833558