

**K233240 GERDX-System**Jun 21, 2024  
267 days to decisionK233240 · Product code: **ODE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k233240/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Suture/plication System, Gastroesophageal Reflux Disease (gerd) (ODE)
Date received	Sep 28, 2023
Decision date	Jun 21, 2024
Days to decision	267 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>G-Surg GmbH</b>
Location	Seeon-Seebruck, DE
Contact	Julian Mair
510(k) history	1 submissions · 1 cleared · 2024-2024

**REGULATORY CONSULTANT**

---

Consulting firm	<b>Novineon CRO GmbH</b>
Contact	Anna Pocsai

Regulatory consulting firm that managed this 510(k) submission on behalf of the applicant. Source: FDA accessdata.fda.gov

---

510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k233240/> Data sourced from FDA 510(k) public records (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. - Generated May 14, 2026