FDA 510(k) Premarket Notification

K233240 GERDX-System

CLEARED

Jun 21, 2024
267 days to decision

K233240 · 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	**G-Surg GmbH**
Location	Seeon-Seebruck, DE
Contact	Julian Mair
510(k) history	1 submissions · 1 cleared · 2024-2024

REGULATORY CONSULTANT

Consulting firm	**Novineon CRO GmbH**
Contact	Anna Pocsai

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