FDA 510(k) Premarket Notification

CLEARED

K240879 EsophyX Z+ Device with SerosaFuse Fasteners and Accessories

Apr 26, 2024
28 days to decision

K240879 · Product code: **ODE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k240879/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Suture/plication System, Gastroesophageal Reflux Disease (gerd) (ODE)
Date received	Mar 29, 2024
Decision date	Apr 26, 2024
Days to decision	28 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	**Endogastric Solutions, Inc.**
Location	Redmond, WA, US
Contact	Shala Famil
510(k) history	11 submissions · 11 cleared · 2007-2024

REGULATORY CONSULTANT

Consulting firm	**Hogan Lovells US LLP**
Contact	John J. Smith

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