

K160960 EsophyX® Z Device with SerosaFuse Fasteners and AccessoriesMay 1, 2016
26 days to decisionK160960 · Product code: **ODE** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160960/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Endoscopic Suture/plication System, Gastroesophageal Reflux Disease (gerd) (ODE)
Date received	Apr 5, 2016
Decision date	May 1, 2016
Days to decision	26 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Endogastric Solutions, Inc.
Location	Redmond, WA, US
Contact	STEVEN J HOFFMAN
510(k) history	11 submissions · 11 cleared · 2007-2024

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160960/>, 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 27, 2026