

# K171307 EsophyX2 HD Device with SerosaFuse Fasteners and Accessories, EsophyX Z Device with SerosaFuse Fasteners and Accessories

Jun 22, 2017  
50 days to decision

K171307 · Product code: **ODE** · Gastroenterology & Urology  
Source: <https://www.510kdatabase.net/k171307/>

## SUBMISSION DETAILS

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Endoscopic Suture/plication System, Gastroesophageal Reflux Disease (gerd) (ODE)
Date received	May 3, 2017
Decision date	Jun 22, 2017
Days to decision	50 days
Third-party review	No
Summary / Statement	Summary

## APPLICANT

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Company	<b>Endogastric Solutions, Inc.</b>
Location	Redmond, WA, US
Contact	Steve Hoffman
510(k) history	11 submissions · 11 cleared · 2007-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)

Device record: <https://www.510kdatabase.net/k171307/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).

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