

**K160654 GastriSail Gastric Positioning System 40 Fr/CH
(13.3mm)**May 4, 2016
57 days to decisionK160654 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k160654/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Mar 8, 2016
Decision date	May 4, 2016
Days to decision	57 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Covidien, LLC
Location	Mansfield, MA, US
Contact	Rebecca Magnanimo
510(k) history	88 submissions · 85 cleared · 2010-2026

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k160654/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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