

**K180605 GastroFlush**Oct 24, 2018  
231 days to decisionK180605 · Product code: **KNT** · Gastroenterology & UrologySource: <https://www.510kdatabase.net/k180605/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Mar 7, 2018
Decision date	Oct 24, 2018
Days to decision	231 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Bionix Development Corporation</b>
Location	Toledo, OH, US
Contact	James Huttner
510(k) history	1 submissions · 1 cleared · 2018-2018

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k180605/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated June 28, 2026