FDA 510(k) Premarket Notification

K180605 GastroFlush

CLEARED

Oct 24, 2018
231 days to decision

K180605 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k180605/

SUBMISSION DETAILS

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

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