

**K915110 FLEXIFLO OVER-THE-GUIDEWIRE GASTROSTOMY
KIT**Apr 14, 1992
153 days to decisionK915110 · Product code: **KNT** · Gastroenterology & Urology
Source: <https://www.510kdatabase.net/k915110/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent - KD
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Nov 13, 1991
Decision date	Apr 14, 1992
Days to decision	153 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	DANIEL HAMILTON
Website	http://www.abbott.com
510(k) history	883 submissions · 868 cleared · 1976-2026

Abbott Laboratories is an American multinational medical devices and health care company headquartered in Abbott Park, Illinois. The company operates in over 160 countries and produces pharmaceuticals, diagnostics, nutritional products, and medical devices. Abbott maintains a substantial FDA 510(k) regulatory record with FDA 510(k) cleared devices from total submissions since 1976. The company's cleared devices span chemistry, microbiology, hematology, immunology, and toxicology categories. The latest clearance in 2025 reflects continued regulatory activity and product de...

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