FDA 510(k) Premarket Notification

K913786 FLEXIFLO OVER-THE-GUIDEWIRE GAST KIT W/CR-BAR BUMP

CLEARED

Nov 5, 1991
74 days to decision

K913786 · Product code: **KNT** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k913786/

SUBMISSION DETAILS

Decision	Substantially Equivalent - K
Submission type	Traditional
Device classification	Tubes, Gastrointestinal (and Accessories) (KNT)
Date received	Aug 23, 1991
Decision date	Nov 5, 1991
Days to decision	74 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...