FDA 510(k) Premarket Notification

K033909 WAVEMAX BALLOON-EXPANDABLE TRANSHEPATIC BILIARY STENT SYSTEM

CLEARED

Feb 17, 2004
62 days to decision

K033909 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k033909/

SUBMISSION DETAILS

Decision	Substantially Equivalent - U
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Dec 17, 2003
Decision date	Feb 17, 2004
Days to decision	62 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	JOANNA KUSKOWSKI
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...