FDA 510(k) Premarket Notification

CLEARED

K041962 XPAND BALLOON-EXPANDABLE TRANSHEPATIC BILIARY STENT SYSTEM, MODELS 20587, 20588, 20589, 20603, 20604, 20605

Oct 1, 2004
72 days to decision

K041962 · Product code: **FGE** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k041962/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Stents, Drains And Dilators For The Biliary Ducts (FGE)
Date received	Jul 21, 2004
Decision date	Oct 1, 2004
Days to decision	72 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...