FDA 510(k) Premarket Notification

K830766 ABBOTT PATIENT ASSIST DEVICE

CLEARED

Mar 29, 1983
19 days to decision

K830766 · Product code: **FKX** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k830766/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Peritoneal, Automatic Delivery (FKX)
Date received	Mar 10, 1983
Decision date	Mar 29, 1983
Days to decision	19 days
Third-party review	No

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
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...