FDA 510(k) Premarket Notification

K874020 ULTRACARE(TM) AUTOMATED PATIENT ASSIST DEVICE

CLEARED

Jan 29, 1988
119 days to decision

K874020 · Product code: **KPF** · Gastroenterology & Urology
Source: https://www.510kdatabase.net/k874020/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Dialysate Delivery, Semi-automatic, Peritoneal (KPF)
Date received	Oct 2, 1987
Decision date	Jan 29, 1988
Days to decision	119 days
Third-party review	No

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	FREDERICK GUSTAFSON
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...