FDA 510(k) Premarket Notification

K011096 ABBOTT ACCLAIM ENCORE, MODEL 12237

CLEARED

May 1, 2001
21 days to decision

K011096 · Product code: **FRN** · General Hospital
Source: https://www.510kdatabase.net/k011096/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Pump, Infusion (FRN)
Date received	Apr 10, 2001
Decision date	May 1, 2001
Days to decision	21 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	FRANK POKROP
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...