FDA 510(k) Premarket Notification

K001616 MODIFICATION TO SYRINGE PREFILLED WITH 0.9% SODIUM CHLORIDE

CLEARED

Jul 27, 2000
63 days to decision

K001616 · Product code: **FOZ** · General Hospital
Source: https://www.510kdatabase.net/k001616/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	May 25, 2000
Decision date	Jul 27, 2000
Days to decision	63 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	**Abbott Laboratories**
Location	Abbott Park, IL, US
Contact	CHRISTINE L LIONHOOD
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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k001616/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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