FDA 510(k) Premarket Notification

K853120 ADDITIVE EXTENSION SYRINGE

CLEARED

Dec 5, 1985
133 days to decision

K853120 · Product code: **FMF** · General Hospital
Source: https://www.510kdatabase.net/k853120/

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Syringe, Piston (FMF)
Date received	Jul 25, 1985
Decision date	Dec 5, 1985
Days to decision	133 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...

510k Database - www.510kdatabase.net
Device record: https://www.510kdatabase.net/k853120/ Data sourced from FDA 510(k) public records (accessdata.fda.gov).
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