

K961552 CVP POLYURETHANE CATHETERFeb 10, 1997
294 days to decisionK961552 · Product code: **FOZ** · General Hospital
Source: <https://www.510kdatabase.net/k961552/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Catheter, Intravascular, Therapeutic, Short-term Less Than 30 Days (FOZ)
Date received	Apr 22, 1996
Decision date	Feb 10, 1997
Days to decision	294 days
Third-party review	No
Summary / Statement	Statement

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	DAVID GUZEK
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...
