

K012975 SOF-TACT DIABETES MANAGEMENT SYSTEMFeb 28, 2002
176 days to decisionK012975 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k012975/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Sep 5, 2001
Decision date	Feb 28, 2002
Days to decision	176 days
Third-party review	No
Summary / Statement	Summary
Other names	SOF-TACT BLOOD GLUCOSE TEST STRIP; PRECISION CONTROL SOLUTIONS

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	JANET S CONNOLLY
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...
