

K001993 SOF-TACT DIABETES MANAGEMENT SYSTEMNov 13, 2000
137 days to decisionK001993 · Product code: **LFR** · Chemistry
Source: <https://www.510kdatabase.net/k001993/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Glucose Dehydrogenase, Glucose (LFR)
Date received	Jun 29, 2000
Decision date	Nov 13, 2000
Days to decision	137 days
Third-party review	No
Summary / Statement	Summary
Other names	SOF-TACT GLUCOSE TEST STRIP; PRECISION CONTROL SOLUTIONS

APPLICANT

Company	Abbott Laboratories
Location	Abbott Park, IL, US
Contact	JOE MAGLIOZZI
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...