

K130094 FREESTYLE PRECISION PRO BLOOD GLUCOSE AND B-KETONE MONITORING SYSTEMJun 27, 2013
168 days to decisionK130094 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k130094/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Jan 10, 2013
Decision date	Jun 27, 2013
Days to decision	168 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Abbott Diabetes Care
Location	Alameda, CA, US
Contact	DAVID G LAMBERT
Website	https://abbottdiabetescare.co.uk/
510(k) history	2 submissions · 2 cleared · 2013-2024

Abbott Diabetes Care develops continuous glucose monitoring and blood glucose management systems. The company operates with a manufacturing facility in Alameda, US, and serves patients managing diabetes globally through innovative Chemistry devices. Abbott Diabetes Care has received FDA 510(k) clearances from total submissions since 2013. The company specializes exclusively in Chemistry devices for glucose and ketone monitoring. Its latest clearance in 2024 reflects continued regulatory activity and product innovation in diabetes care technology. The company's portfolio i...