

**K233861 Libre Rio Continuous Glucose Monitoring System**Jun 7, 2024  
184 days to decisionK233861 · Product code: **SBH** · Chemistry  
Source: <https://www.510kdatabase.net/k233861/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Integrated Continuous Glucose Monitor For Non-intensive Glucose Management, Over-the-counter (SBH)
Date received	Dec 6, 2023
Decision date	Jun 7, 2024
Days to decision	184 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Abbott Diabetes Care</b>
Location	Alameda, CA, US
Contact	Tenzin Ngadon
Website	<a href="https://abbottdiabetescare.co.uk/">https://abbottdiabetescare.co.uk/</a>
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...

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