

**K191286 CONTOUR® NEXT Blood Glucose Monitoring System,  
CONTOUR® NEXT USB Blood Glucose Monitoring System,  
CONTOUR® NEXT ONE Blood Glucose Monitoring System,  
CONTOUR® NEXT EZ Blood Glucose Monitoring System,  
CONTOUR® NEXT LINK Wireless Blood Glucose Monitoring  
System**Nov 8, 2019  
179 days to decisionK191286 · Product code: **NBW** · Chemistry  
Source: <https://www.510kdatabase.net/k191286/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	May 13, 2019
Decision date	Nov 8, 2019
Days to decision	179 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

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Company	<b>Ascensia Diabetes Care</b>
Location	Mishawaka, IN, US
Contact	Stacie Geffner-Atiya
510(k) history	5 submissions · 5 cleared · 2016-2024

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k191286/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://accessdata.fda.gov)).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at [accessdata.fda.gov](http://accessdata.fda.gov). - Generated May 26, 2026