

K193407 Contour® next GEN Blood Glucose Monitoring SystemDec 23, 2021
745 days to decisionK193407 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k193407/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 9, 2019
Decision date	Dec 23, 2021
Days to decision	745 days
Third-party review	No
Combination product	No
PCCP authorized	No
Summary / Statement	Summary

APPLICANT

Company	Ascensia Diabetes Care
Location	Mishawaka, IN, US
Contact	Colleen Burdel
510(k) history	5 submissions · 5 cleared · 2016-2024

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