

**K062347 ASCENSIA BREEZE 2 BLOOD GLUCOSE
MONITORING SYSTEM**Nov 22, 2006
104 days to decisionK062347 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k062347/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Aug 10, 2006
Decision date	Nov 22, 2006
Days to decision	104 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

Company	Bayer Healthcare, LLC
Location	New York, NY, US
Contact	MARC HENN
510(k) history	46 submissions · 46 cleared · 2003-2018

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