

K043311 ASCENSIA ELITE DIABETES CARE SYSTEMDec 22, 2004
21 days to decisionK043311 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k043311/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Dec 1, 2004
Decision date	Dec 22, 2004
Days to decision	21 days
Third-party review	No
Summary / Statement	Summary

APPLICANT

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

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