

K043158 ASCENSIA BRIO BLOOD GLUCOSE MONITORING SYSTEMDec 22, 2004
37 days to decisionK043158 · Product code: **NBW** · Chemistry
Source: <https://www.510kdatabase.net/k043158/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	System, Test, Blood Glucose, Over The Counter (NBW)
Date received	Nov 15, 2004
Decision date	Dec 22, 2004
Days to decision	37 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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