

**K042080 TRACKEASE SMART SYSTEM BLOOD GLUCOSE SYSTEM**Aug 19, 2004  
16 days to decisionK042080 · Product code: **JJX** · Chemistry  
Source: <https://www.510kdatabase.net/k042080/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Special
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Aug 3, 2004
Decision date	Aug 19, 2004
Days to decision	16 days
Third-party review	No
Summary / Statement	Statement

**APPLICANT**

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Company	<b>Home Diagnostics, Inc.</b>
Location	Eatontown, NJ, US
Contact	KAREN DEVINCENT
510(k) history	22 submissions · 22 cleared · 1985-2009

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k042080/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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