

**K861855 HYDROXYBUTYRATE DEHYDROGENASE (HBD)  
REAGENT SET**Jun 16, 1986  
33 days to decisionK861855 · Product code: JKF · Chemistry  
Source: <https://www.510kdatabase.net/k861855/>**SUBMISSION DETAILS**

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Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Dinitrophenyl Hydrazone Measurement (colorimetric), Hydroxybutyric Dehydroge (JKF)
Date received	May 14, 1986
Decision date	Jun 16, 1986
Days to decision	33 days
Third-party review	No

**APPLICANT**

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Company	<b>Sterling Diagnostics, Inc.</b>
Location	Sterling Heights, MI, US
Contact	DAVID L CALLENDER
510(k) history	41 submissions · 41 cleared · 1985-1993

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510k Database - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k861855/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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