

**K910108 GDS ENZYMATIC B-HYDROXYBUTYRATE REAGENT
MODIFIED**Mar 4, 1991
53 days to decisionK910108 · Product code: **JIN** · Chemistry
Source: <https://www.510kdatabase.net/k910108/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitroprusside, Ketones (urinary, Non-quant.) (JIN)
Date received	Jan 10, 1991
Decision date	Mar 4, 1991
Days to decision	53 days
Third-party review	No

APPLICANT

Company	Gds Diagnostics
Location	Elkhart, IN, US
Contact	DE CASTRO
510(k) history	4 submissions · 4 cleared · 1989-1993

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