

**K895528 GEL ALKALINE PHOSPHATASE ISOENZYME
CONTROL NO.5104**Oct 25, 1989
49 days to decisionK895528 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k895528/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Single (specified) Analyte Controls (assayed And Unassayed) (JJX)
Date received	Sep 6, 1989
Decision date	Oct 25, 1989
Days to decision	49 days
Third-party review	No

APPLICANT

Company	Helena Laboratories
Location	Mchenry, IL, US
Contact	PAT FRANKS
510(k) history	280 submissions · 280 cleared · 1978-2013

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k895528/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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