

**K910639 SYSTEMATE ALKALINE PHOSPHATASE(EPOS APPL)
#65483**

Apr 12, 1991
58 days to decision

K910639 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k910639/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Feb 13, 1991
Decision date	Apr 12, 1991
Days to decision	58 days
Third-party review	No

APPLICANT

Company	Em Diagnostic Systems, Inc.
Location	Walker, MI, US
Contact	ANNA G BENTLEY
510(k) history	288 submissions · 288 cleared · 1984-1994

510k Database - www.510kdatabase.net

Device record: <https://www.510kdatabase.net/k910639/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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