

**K895250 SYSTEMATE(TM) ALKALINE PHOSPHATASE ITEM
#65402**

Oct 31, 1989
71 days to decision

K895250 · Product code: **CJE** · Chemistry
Source: <https://www.510kdatabase.net/k895250/>

SUBMISSION DETAILS

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Nitrophenylphosphate, Alkaline Phosphatase Or Isoenzymes (CJE)
Date received	Aug 21, 1989
Decision date	Oct 31, 1989
Days to decision	71 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/k895250/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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