

**K862704 EMDS(TM) ELEVATED BILIRUBIN CALIBRATOR #
67627/95**Aug 19, 1986
35 days to decisionK862704 · Product code: **JIS** · Chemistry
Source: <https://www.510kdatabase.net/k862704/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Primary (JIS)
Date received	Jul 15, 1986
Decision date	Aug 19, 1986
Days to decision	35 days
Third-party review	No

APPLICANT

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

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