

K882450 GEM-STAT W/COMP. GEM-STATPAK/GEM-CHECK & CRIT CHK.Jul 28, 1988
44 days to decisionK882450 · Product code: **JJE** · Chemistry
Source: <https://www.510kdatabase.net/k882450/>**SUBMISSION DETAILS**

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Analyzer, Chemistry (photometric, Discrete), For Clinical Use (JJE)
Date received	Jun 14, 1988
Decision date	Jul 28, 1988
Days to decision	44 days
Third-party review	No

APPLICANT

Company	Diamond Sensor Systems
Location	Ann Arbor, MI, US
Contact	ENZER, PHD
510(k) history	3 submissions · 3 cleared · 1987-1988

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k882450/> Data sourced from FDA 510(k) public records (accessdata.fda.gov).

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