

K864825 AMYLASE COLORIMETRIC PROCEDUREFeb 20, 1987
73 days to decisionK864825 · Product code: **JFJ** · Chemistry
Source: <https://www.510kdatabase.net/k864825/>**SUBMISSION DETAILS**

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|-----------------------|------------------------------------|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Catalytic Methods, Amylase (JFJ) |
| Date received | Dec 9, 1986 |
| Decision date | Feb 20, 1987 |
| Days to decision | 73 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Data Medical Associates, Inc. |
| Location | Mchenry, IL, US |
| Contact | MARJORIE B POTTS |
| 510(k) history | 111 submissions · 111 cleared · 1978-1999 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k864825/>; Data sourced from FDA 510(k) public records (accessdata.fda.gov).510k Database is an independent platform not affiliated with the U.S. Food and Drug Administration. Always verify at accessdata.fda.gov. - Generated June 29, 2026