

K831523 BETA SCAN NORMAL CONTROL SOLUTIONJul 19, 1983
68 days to decisionK831523 · Product code: **JJX** · Chemistry
Source: <https://www.510kdatabase.net/k831523/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Single (specified) Analyte Controls (assayed And Unassayed) (JJX) |
| Date received | May 12, 1983 |
| Decision date | Jul 19, 1983 |
| Days to decision | 68 days |
| Third-party review | No |

APPLICANT

| | |
|----------------|---|
| Company | Orange Medical Instruments, Inc. |
| Location | Mchenry, IL, US |
| 510(k) history | 12 submissions · 12 cleared · 1982-1986 |

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k831523/> 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 May 27, 2026