

**K951964 SYNCHRON ENZYME VALIDATOR SET**Jun 29, 1995  
63 days to decisionK951964 · Product code: **JIS** · Chemistry  
Source: <https://www.510kdatabase.net/k951964/>**SUBMISSION DETAILS**

---

Decision	Substantially Equivalent (Cleared)
Submission type	Traditional
Device classification	Calibrator, Primary (JIS)
Date received	Apr 27, 1995
Decision date	Jun 29, 1995
Days to decision	63 days
Third-party review	No
Summary / Statement	Summary

**APPLICANT**

---

Company	<b>Beckman Instruments, Inc.</b>
Location	Mchenry, IL, US
Contact	DON W HART
Website	<a href="https://www.beckman.com">https://www.beckman.com</a>
510(k) history	281 submissions · 281 cleared · 1976-1998

---

**510k Database** - [www.510kdatabase.net](http://www.510kdatabase.net)Device record: <https://www.510kdatabase.net/k951964/> Data sourced from FDA 510(k) public records ([accessdata.fda.gov](http://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](http://accessdata.fda.gov). - Generated May 22, 2026