

**K992349 VITROS IMMUNODIAGNOSTIC PRODUCTS TROPONIN
I RANGE VERIFIERS**Aug 24, 1999
41 days to decisionK992349 · Product code: **JJY** · Chemistry
Source: <https://www.510kdatabase.net/k992349/>**SUBMISSION DETAILS**

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|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Jul 14, 1999 |
| Decision date | Aug 24, 1999 |
| Days to decision | 41 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Ortho-Clinical Diagnostics, Inc. |
| Location | Rochester, NY, US |
| Contact | MARLENE A SHULMAN |
| 510(k) history | 106 submissions · 104 cleared · 1997-2025 |

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