

**K101809 FUJIREBIO DIAGNOSTICS TUMOR MARKER
CONTROL MODEL 108-20**Oct 5, 2010
98 days to decisionK101809 · Product code: JJY · Immunology
Source: <https://www.510kdatabase.net/k101809/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Multi-analyte Controls, All Kinds (assayed) (JJY) |
| Date received | Jun 29, 2010 |
| Decision date | Oct 5, 2010 |
| Days to decision | 98 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

| | |
|----------------|---|
| Company | Fujirebio Diagnostics, Inc. |
| Location | North Caldwell, NJ, US |
| Contact | STACEY DOLAN |
| 510(k) history | 45 submissions · 43 cleared · 1989-2025 |

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