

**K103676 FUJIREBIO DIAGNOSTICS TUMOR MARKER
CONTROL**Jul 19, 2011
215 days to decisionK103676 · Product code: **OIU** · Immunology
Source: <https://www.510kdatabase.net/k103676/>**SUBMISSION DETAILS**

| | |
|-----------------------|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Epithelial Ovarian Tumor Associated Antigen (he4) (OIU) |
| Date received | Dec 16, 2010 |
| Decision date | Jul 19, 2011 |
| Days to decision | 215 days |
| Third-party review | No |
| Summary / Statement | Summary |

APPLICANT

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

510k Database - www.510kdatabase.netDevice record: <https://www.510kdatabase.net/k103676/> 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 19, 2026