FDA 510(k) Premarket Notification

**CLEARED**

# K151378 Lumipulse G HE4 Immunoreaction Cartridges, Lumipulse G HE4 Calibrators

Nov 24, 2015
186 days to decision

K151378 · Product code: **OIU** · Immunology
Source: https://www.510kdatabase.net/k151378/

## SUBMISSION DETAILS

| | |
|---|---|
| Decision | Substantially Equivalent (Cleared) |
| Submission type | Traditional |
| Device classification | Test, Epithelial Ovarian Tumor Associated Antigen (he4) (OIU) |
| Date received | May 22, 2015 |
| Decision date | Nov 24, 2015 |
| Days to decision | 186 days |
| Third-party review | No |
| Summary / Statement | Summary |

## APPLICANT

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