JUL 19 2011

FUJIREBIO® Diagnostics, Inc.

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is: K103676

Submitter Information

Address:	Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA 19355
Contact person:	Diana L Dickson (610) 240-3917 dicksond@fdi.com

Summary preparation date: July 18, 2011

Name of Device

510(k) number:	K072939
Trade/Proprietary Name:	HE4 EIA Kit
Common/Usual Name:	Tumor-associated Antigen Immunological Test System.
Regulation Number:	21 CFR §866.6010
Regulatory Class:	Class II
Product Code:	OIU, epithelial ovarian tumor associated antigen test (HE4)
510(k) number:	K101809
Trade/Proprietary Name:	Fujirebio Diagnostics Tumor Marker Control
Common/Usual Name:	Quality control material (assayed and unassayed).
Regulation Number:	21 CFR 862.1660
Regulatory Class:	Class I, reserved
Product Code:	JJY, Multi-Analyte Controls, All kinds, (Assayed)

Predicate Device

HE4 EIA (K072939)

FUJIREBIO® Diagnostics, Inc.

Purpose of Submission

The purpose of the Fujirebio Diagnostics Tumor Marker Control (for use with HE4 EIA) 510(k) submission is to replace the current HE4 EIA kit controls (cleared under K072939) with the Fujirebio Diagnostics Tumor Marker Control (cleared under K101809).

The Fujirebio Diagnostics Tumor Marker Controls are used for validation of each HE4 EIA assay series. The HE4 EIA results should be considered valid if the mean HE4 values of control duplicates are within the specified HE4 EIA ranges indicated on the Assigned Value Sheet provided with the Fujirebio Diagnostics Tumor Marker Controls.

Intended Use of the Fujirebio Diagnostics Tumor Marker Control

For In Vitro Diagnostic Use Only.
Fujirebio Diagnostics Tumor Marker Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analytes listed in the lot specific assigned values sheet.

A comparison of the features of the Fujirebio Diagnostics Tumor Marker Control and the Predicate Device are as follows:

Similarities		
	Fujirebio Diagnostics Tumor Marker Control (K101809)	**HE4 EIA kit controls (K072939)**
Intended Purpose	Validation of each HE4 EIA assay series. The HE4 EIA results should be considered valid if the mean HE4 values of control duplicates are within the specified HE4 EIA ranges	Validation of each HE4 EIA assay series. The HE4 EIA results should be considered valid if the mean HE4 values of control duplicates are within the specified HE4 EIA ranges
Supplier	Manufactured by Fujirebio Diagnostics	Manufactured by Fujirebio Diagnostics
Matrix	Human Serum	Human Serum
Form	Lyophilized	Lyophilized
HE4 Analyte	Purified, recombinant antigen	Purified, recombinant antigen
Control Levels	2	2
Storage (unopened)	Store the kit at 2–8°C.	Store the kit at 2–8°C.
Shelf Life (unopened)	18 months	18 months

FUJIREBIO® Diagnostics, Inc.

Differences		
	Fujirebio Diagnostics Tumor Marker Control (K101809)	**HE4 EIA kit controls (K072939)**
Controls Supplied	Sold Separately	Sold with HE4 EIA kit
Analyte (s)	HE4 (Human Epididymis Protein 4) AFP (Alpha-Fetoprotein) CA 15-3 CA 19-9 CA 125 CEA (Carcinoembryonic Antigen) Ferritin HE4 (Human Epididymis Protein 4) PSA (Prostate Specific Antigen) Free PSA	HE4 (Human Epididymis Protein 4)
Target HE4 Concentrations	75 and 500 pM*	50 and 400 pM*
Target HE4 Ranges	Ranges of expected results indicated on the Assigned Value Sheet provided with the Fujirebio Diagnostics Tumor Marker Controls.	Ranges of expected results are indicated on the vial labels.
Reconstitution Volume	3.0 mL distilled or deionized water	1.0 mL distilled or deionized water
Stability after Reconstitution	14 days at 2–8°C 60 days at -20°C or below	4 weeks at 2–8°C 4 months at -20°C or below

*Target concentration differences are acceptable - the claimed HE4 EIA range is 15 – 900 pM, with an upper limit of normal of 150 pM. (Refer to HE4 EIA package insert)

Value Assignment comparisons:

Fujirebio Diagnostics Tumor Marker Control (K101809)	**HE4 EIA kit controls (K072939)**
24 replicate analyses collected in 4 independent runs	26 replicate analyses collected in 2 independent runs
Different HE4 EIA kit reagent combinations in each run	Same HE4 EIA kit reagent combination in each run
CV <8% within run. Mean value for each run within ± 2SD for other 3 runs.	Total CV% $\leq$ 5
Assigned range for HE4 EIA Control Level 1: Total Mean ± 2SD but not less than ± 30%	Assigned range HE4 EIA kit Control Level 1: Total Mean ± 30%
Assigned range for HE4 EIA Control Level 2: Total Mean ± 2SD but not less than ± 25%	Assigned range HE4 EIA kit Control Level 2: Total Mean ± 20%

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Fujirebio Diagnostics, Inc.
c/o Ms. Diana Lyn Dickson
Regulatory Affairs Manager
201 Great Valley Parkway
Malvern, PA 19355

JUL 19 2011

Re: k103676
Trade/Device Name: HE4 EIA kit
Fujirebio Diagnostics Tumor Marker Control
Regulation Number: 21 CFR §866.6010
Regulation Name: Tumor-associated Antigen Immunological Test
Regulatory Class: Class II
Product Code: OIU, JJY
Dated: July 7, 2011
Received: July 8, 2011

Dear Ms. Dickson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Maria M. Chan

Maria M. Chan, Ph.D.
Director
Division of Immunology and Hematology Devices
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k103676

Device Name: HE4 EIA

Indications For Use:

The HE4 EIA is an enzyme immunometric assay for the quantitative determination of HE4 in human serum. The assay is to be used as an aid in monitoring recurrence or progressive disease in patients with epithelial ovarian cancer. Serial testing for patient HE4 assay values should be used in conjunction with other clinical methods used for monitoring ovarian cancer.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Leena Philip

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k103676

Indications for Use

510(k) Number (if known): k103676

Device Name: Fujirebio Diagnostics Tumor Marker Controls

Indications For Use:

For In Vitro Diagnostic Use Only.
Fujirebio Diagnostics Tumor Marker Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analytes listed in the lot specific assigned values sheet.

Prescription Use __X____ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510K k103676