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: K101809

Submitter Information

OCT - 5 2010

Address:	Fujirebio Diagnostics, Inc. 201 Great Valley Parkway Malvern, PA 19355
Contact person:	Stacey Dolan (610) 240-3843 dolans@fdi.com

Summary preparation date: October 5, 2010

Name of Device

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

Predicate Device

Bio-Rad Lyphochek® Tumor Marker Plus Control (K082036)
For HE4: ARCHITECT HE4 Control Kit (K093957)

Summary and Principle

This quality control product can be used as an objective judgment of the laboratory's procedures and personnel techniques. It is a valuable tool to assess good laboratory practices. Two levels of control are available to compare observations with expected ranges therefore assuring consistent performance of the testing systems within the clinical range.

FUJIREBIO® Diagnostics, Inc.

Intended 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 analysis of AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, HE4, PSA and Free PSA.

Statement of Substantial Equivalence

The Fujirebio Diagnostics Tumor Marker Control is intended for use as a quantitative, assayed control serum to monitor the procedures used in the laboratory for testing the analytes listed in the lot specific assigned values sheet.

The Fujirebio Diagnostics Tumor Marker Control is substantially equivalent to the Lyphochek Tumor Marker Plus Control*. Each of the devices are assayed quality control material and are used to monitor the precision of laboratory testing procedures for the analytes listed in their respective package insert.
*Note: For HE4, the Fujirebio Diagnostics Tumor Marker Control is substantially equivalent to the ARCHITECT HE4 Control Kit.

The regulatory submission is prepared pursuant to Title 21CFR § 862.1660.

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

FUJIREBIO Diagnostics, Inc.

Similarities		
	Fujirebio Diagnostics Tumor Marker Control (Proposed Device) K101809	**Bio-Rad Lyphochek® Tumor Marker Plus Control (Predicate Device) K082036** **For HE4: ARCHITECT HE4 Control Kit K093957**
Device Type	*In vitro* diagnostic	*In vitro* diagnostic
Classification	Class I, reserved	Class I, reserved
CFR section	862.1660	862.1660
Product Code	JJY	JJY
Product Usage	Clinical and Hospital laboratories	Clinical and Hospital laboratories
Intended 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 analysis of AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, HE4, PSA and Free PSA.	Lyphochek Tumor Marker Plus Control is intended for use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert. The ARCHITECT HE4 Controls are used for the verification of the accuracy and precision of the ARCHITECT *i* System when used for the quantitative determination of HE4 antigen in human serum.
Matrix	Human Serum	Human Serum (For HE4, matrix is protein buffer)
Form	Lyophilized	Lyophilized (For HE4, Liquid)
Analytes	AFP, CA 15-3, CA 19-9, CA 125, CEA, Ferritin, PSA, Free PSA	AFP, CA 15-3, CA 19-9, CA 125, CEA, Ferritin, PSA, Free PSA
Stability – Reconstituted at 2-8˚C	14 days at 2-8˚C, except Free PSA which is stable for 7 days	14 days at 2-8˚C, except Free PSA which is stable for 7 days

FUJIREBIO Diagnostics, Inc.

Differences		
	Fujirebio Diagnostics Tumor Marker Control (Proposed Device) K101809	**Bio-Rad Lyphochek® Tumor Marker Plus Control (Predicate Device) K082036** **For HE4: ARCHITECT HE4 Control Kit K093957**
Number of Levels	2	3
PSA Stability (reconstituted)	Total PSA – 14 days Free PSA – 7 days	Total PSA – 7 days Free PSA – 7 days
Reconstitution Volume	3.0 mLs	2.0 mLs
Analytes	HE4 (Human Epididymis Protein 4)	ACTH, Aldosterone, Beta-2-Microglobulin, CA 27.29, Calcitonin, hCG, Prolactin, Prostatic Acid Phosphatase, and Thyroglobulin
Stability (unopened)	18 months at 2-8˚C	3 years at 2-8˚C (For HE4, 9 Months)
Stability – Reconstituted at 2-8˚C	CEA and Total PSA 14 days at 2-8˚C	CEA 11 days at 2-8˚C Total PSA 7 days at 2-8˚C
Stability – Reconstituted at ≤-20˚C	All analytes are stable for 60 days when stored at ≤-20˚C	All analytes are stable for 30 days when stored at ≤-20˚C
Stability – Freeze/thaw	May be frozen and thawed repeatedly for up to 9 cycles	No claim made for freeze/thaw stability
Endogenous (Non-Spiked) analytes	CA 242 and CA 27.29*	None

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
10903 New Hampshire Avenue
Building 66
Silver Spring, MD 20993

Fujirebio Diagnostics, AB
c/o Ms. Christina Hall
Director, Quality and Regulatory Affairs
Majnabbe Terminal
Gothenburg, Sweden, SE 41455, SW

OCT 05 2010

Re: k101809
Trade/Device Name: Fujirebio Diagnostics Tumor Marker Controls
Regulation Number: 21 CFR§862.1660
Regulation Name: Quality Control Material, Assayed and Unassayed
Regulatory Class: Class I (Reserved)
Product Code: JJY
Dated: September 3, 2010
Received: September 9, 2010

Dear Ms. Hall:

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,

for 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 Form K101809

510(k) Number (if known): K101809

Device Name: Fujirebio Diagnostics Tumor Marker Controls

OCT - 5 2010

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 analysis of AFP, CA15-3, CA19-9, CA125, CEA, Ferritin, HE4, PSA and Free PSA.

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

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

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

Reena Philip

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k101809