MAY 2 7 2011

K 110641

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: _____.

Submitter Information

Address: Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA 19355

Contact person: Stacey Dolan
(610) 240-3843
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Summary preparation date: March 2, 2011

Name of Device

Trade/Proprietary Name: Fujirebio Diagnostics Vitamin D Control

Common/Usual Name: Quality control material (assayed and unassayed).

Regulation Number: 21 CFR 862.1660

Regulatory Class: Class I

Product Code: JJX

Predicate Device

Bio-Rad Liquichek™ Specialty Immunoassay Control (k043108) – 25-OH Vitamin D component

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. Three levels of control are available to compare observations with expected ranges therefore assuring consistent performance of the testing system within the clinical range.

Intended Use

Fujirebio Diagnostics Vitamin D Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of Vitamin D.

FUJIREBIO® Diagnostics, Inc.

Statement of Substantial Equivalence

Fujirebio Diagnostics Vitamin D Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of Vitamin D.

The Fujirebio Diagnostics Vitamin D Control is substantially equivalent to the 25-OH Vitamin D component of the Bio-Rad Liquichek™ Specialty Immunoassay Control. Both of the devices are quality control serum and are used to monitor the precision of laboratory testing procedures for Vitamin D.

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

A comparison of the features of the Fujirebio Diagnostics Vitamin D Control and the 25-OH Vitamin D component of Bio-Rad Liquichek™ Specialty Immunoassay Control are as follows:

Similarities		
	Fujirebio Diagnostics Vitamin D Control (Proposed Device)	**Bio-Rad Liquichek™ Specialty Immunoassay Control – 25-OH Vitamin D (Predicate Device) K043108**
Device Type	*In vitro* diagnostic	*In vitro* diagnostic
Classification	Class I	Class I
CFR section	862.1660	862.1660
Product Usage	Clinical and Hospital laboratories	Clinical and Hospital laboratories
Intended Use	The Fujirebio Diagnostics Vitamin D Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of Vitamin D.	Liquichek Specialty Immunoassay Control is intended for use as a quality control serum to monitor the precision of laboratory testing procedures for the analytes listed in the package insert.
Analyte	25(OH) Vitamin D	25(OH) Vitamin D
Matrix	Human Serum, protein (bovine), purified biochemical materials, and chemicals. Proclin 300 and Gentamicin as preservatives.	Human Serum with added constituents of human and animal origin, chemicals, stabilizers and preservatives.
Number of Levels	3	3

Differences		
	Fujirebio Diagnostics Vitamin D Control (Proposed Device)	**Bio-Rad Liquichek™ Specialty Immunoassay Control – 25-OH Vitamin D (Predicate Device) K043108**
Reconstitution Volume	2.0 mLs	5.0 mLs
Vitamin D Analyte Forms	25(OH) Vitamin D2 25(OH) Vitamin D3	25(OH) Vitamin D3
Other Analytes	Contains only 25(OH) Vitamin D	Contains also: Anti-Tg Anti-TPO C-peptide Erythropoietin (EPO) Intact PTH (iPTH) IGF-I Osteocalcin
Storage (unopened)	12 months at 2 to 8°C	2 years at -20°C to -70°C
Form	Lyophilized	Liquid
Product Code	JJX	JJY

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. Stacey Dolan
Manager, Regulatory Affairs
201 Great Valley Parkway
Malvern, PA 19355

MAY 2 7 2011

Re: k110641
Trade Name: Fujirebio Diagnostics Vitamin D Control
Regulation Number: 21 CFR §862.1660
Regulation Name: Quality control material (assayed and unassayed).
Regulatory Class: Class I, reserved
Product Codes: JJX
Dated: March 03, 2011
Received: March 04, 2011

Dear Ms. Dolan:

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 either class II (Special Controls) or class III (PMA), 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).

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,

Courtney Harper, Ph.D.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: Fujirebio Diagnostics Vitamin D Control

Indications for Use:

Fujirebio Diagnostics Vitamin D Control is intended for use as an assayed control serum to monitor the precision of laboratory testing procedures for the analysis of Vitamin D.

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)

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

510(k) K110641