

MAY 27 2011

K 110641

Premarket Notification (510(k))
Tumor Marker Control



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
dolans@fdi.com

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.

Premarket Notification (510(k))
Tumor Marker Control



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	<i>In vitro</i> diagnostic	<i>In vitro</i> 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

Premarket Notification (510(k))
Tumor Marker Control



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 27 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.

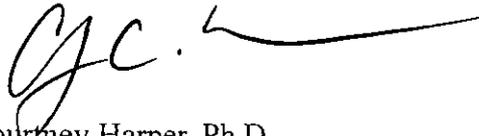
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 –

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,

A handwritten signature in black ink, appearing to read 'CHC', followed by a long horizontal line extending to the right.

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

Page 1 of 1



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 27 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.

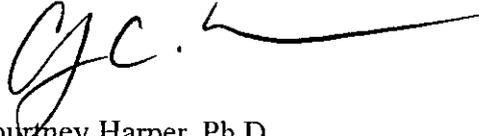
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

Page 2 –

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,

A handwritten signature in black ink, appearing to read 'CH', with a long horizontal line extending to the right.

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

Page 1 of 1



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

U.S. Food and Drug Administration
 Center for Devices and Radiological Health
 Document Control Center WO66-G609
 10903 New Hampshire Avenue
 Silver Spring, MD 20993-0002

March 07, 2011

FUJIREBIO DIAGNOSTICS, INC
 940 CROSSROADS BLVD.
 SEGUIN, TEXAS 78155
 ATTN: JOHN GORMLEY

510k Number: K110641

Received: 3/4/2011

Product: FUJIREBIO DIAGNOSTICS VITAMIN

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act(Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. **YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.**

On May 21, 2004, FDA issued a Guidance for Industry and FDA Staff entitled, "FDA and Industry Actions on Premarket Notification (510(k)) Submissions: Effect on FDA Review Clock and Performance Assessment". The purpose of this document is to assist agency staff and the device industry in understanding how various FDA and industry actions that may be taken on 510(k)s should affect the review clock for purposes of meeting the Medical Device User Fee and Modernization Act. Please review this document at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089735.htm>.

In future premarket submissions, we encourage you to provide an electronic copy of your submission. By doing so, you will save FDA resources and may help reviewers navigate through longer documents more easily. Under CDRH's eCopy Program, you may replace one paper copy of any premarket submission (e.g., 510(k), IDE, PMA, HDE) with an electronic copy. For more information about the program, including the formatting requirements, please see <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/PremarketSubmissions/ucm134508.htm>.

We remind you that Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) amended the PHS Act by adding new section 402(j) (42 U.S.C. § 282(j)), which expanded the current database known as ClinicalTrials.gov to include mandatory registration and reporting of results for applicable clinical trials of human drugs (including biological products) and devices. Section 402(j) requires that a certification form (<http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3674.pdf>) accompany 510(k)/HDE/PMA submissions. The agency has issued a draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration

Amendments Act of 2007" (http://www.fda.gov/oc/initiatives/fdaaa/guidance_certifications.html). According to the draft guidance, 510(k) submissions that do not contain clinical data do not need the certification form.

The Clinical Laboratory Improvement Amendments of 1988 (CLIA) requires the categorization of commercially marketed test systems by level of complexity. If your device is a test system that requires categorization you will be notified of your complexity as an enclosure with any clearance letter.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Also, please note the new Blue Book Memorandum regarding Fax and E-mail Policy entitled, "Fax and E-Mail Communication with Industry about Premarket Files Under Review". Please refer to this guidance for information on current fax and e-mail practices at <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089402.htm>.

Please ensure that whether you submit a 510(k) Summary as per 21 CFR 807.92, or a 510(k) Statement as per 21 CFR 807.93, it meets the content and format regulatory requirements.

You should be familiar with the regulatory requirements for medical device available at Device Advice <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm>". If you have other procedural questions, or want information on how to check on the status of your submission, please contact DSMICA at (301)796-7100 or its toll-free number (800)638-2041, or at their Internet address <http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm> or the 510k staff at (301)796-5640 .

Sincerely,

510(k) Staff

Submitter:

John Gomley
General Manager
Fujirebio Diagnostics, Inc.
940 Crossroads Blvd
Seguin, TX, 78155, US
Phone: (800) 531-7963
Fax: (830) 372-4130

Secondary Contact:

Stacey Dolan
Regulatory Affairs Specialist
Fujirebio Diagnostics, Inc.
201 Great Valley Parkway
Malvern, PA, 19355, US
Phone: (610) 240-3843
Fax: (610) 240-3803

March 3, 2011

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Attn: eSubmitter Team
Document Mail Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

Dear Sir or Madam:

This submission dated March 3, 2011, is filed pursuant to the In Vitro Diagnostic Device Evaluation and Safety program's Electronic Review (eReview).

The submission is a(n) **510(k), Original Submission, Traditional** referring to the product, Assayed Quality Control Material also known as trade name(s): Fujirebio Diagnostics Vitamin D Control with model(s): 2130152. The classification panel for this submission is CLINICAL CHEM ISTRY.

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.
--

The prior submissions that are related to this release are as follows: N/A.

The devices to which substantial equivalence is claimed are as follows: K043108 - 25(OH) Vitamin D Component of Bio-Rad Liquichek Specialty Immunoassay Control.

User Fee Payment ID: (b)(4)

Truth and Accuracy Statement

To the best of my knowledge, the data and information submitted in this premarket notification are truthful and accurate, and no material fact has been omitted (as required by 21 CFR 807.87).

Sincerely,

John Gomley
General Manager
Fujirebio Diagnostics, Inc.

Submission Report

Section: Admin

1.0 Type of Submission

Introduction

*Department of Health and Human Services
 Food and Drug Administration*

CDRH PreMarket Review Submission Cover Sheet

*Form Approval
 OMB No. 0910-0120*

Note:	Please be advised that: 1) under 21 CFR 807.7(1), we may request any additional information that is necessary to reach a determination regarding substantial equivalence and 2) supportive raw data may be provided as attachments to this submission.
Information:	Whenever possible, please enter descriptions in executive summary format because this information will be used to generate the FDA Decision summary. If additional information is needed, please attach the appropriate file.

Section A	Type of Submission
------------------	---------------------------

Submission Type	*	510(k)
▪ Submission Sub-Type	*	Original Submission
- Submission Sub-Sub-Type	*	Traditional
Enter the original submission number.		
Is this a bundled submission?	*	No

User Fee Payment ID Number	*	(b)(4)
----------------------------	---	--------

[MDUFMA Cover Sheet](#)

Please attach the completed MDUFMA Cover Sheet.		*
File Attachment	Fujiirebio Diagnostics Vitamin D Control MDUFMA Cover Sheet	

2.0 Contact Information

Section B	Primary Contact (Submitter, Applicant, or Sponsor)
------------------	---

Primary Contact Information		*
<i>Contact Information:</i>		
Contact Name	Mr. John Gormley	
Occupation Title	General Manager	
Email Address	JGormley@fdi.com	
<i>Address</i>		
Establishment Name	Fujirebio Diagnostics, Inc.	
Division Name		
Address	940 Crossroads Blvd Seguin, TX, 78155, US	
Telephone Number	(800) 531-7963	
Fax Number	(830) 372-4130	

Section C	Secondary Contact (Applicant Correspondent, US Agent, or Consultant)
------------------	---

Secondary Contact Information	
<i>Contact Information:</i>	
Contact Name	Mrs Stacey Dolan
Occupation Title	Regulatory Affairs Specialist
Email Address	dolans@fdi.com
<i>Address</i>	
Establishment Name	Fujirebio Diagnostics, Inc.
Division Name	
Address	201 Great Valley Parkway Malvern, PA, 19355, US
Telephone Number	(610) 240-3843
Fax Number	(610) 240-3803

Who should be contacted for issues related to this submission?	* Secondary Contact
--	---------------------

Section D	Manufacturing Location (Physical Location of the Manufacturing Plant)
------------------	--

Manufacturing Location (Optional)	
<i>Establishment Information:</i>	
Establishment Name	Fujirebio Diagnostics, Inc.
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	1643621
Owner/Operator Number	(b)(4)
<i>Physical Location:</i>	
Address	940 Crossroads Blvd Seguin, TX, 78155, US
Telephone Number	(800) 531-7963
Fax Number	(830) 372-4130

3.0 Reason for Submission

Section D3	Reason for Submission - 510(k)
-------------------	---------------------------------------

New Device	*	Yes
Additional or Expanded Indications		
Change in technology		
If additional information is required, attach file.		

Section E	Additional Information on 510(k) submissions
------------------	---

Information on Device to which substantial equivalence is claimed. 510(k) Number - Trade or Proprietary or Model Name *

Item 1	K043108 - 25(OH) Vitamin D Component of Bio-Rad Liquichek Specialty Immunoassay Control
--------	---

For this submission, are you including a 510(k) Statement or Summary? * 510(k) Summary

Enter your 510(k) Summary or Statement. *

See attached file:

Fujirebio Diagnostics Vitamin D Control - 510k Summary

File Attachment	Fujirebio Diagnostics Vitamin D Control - 510k Summary
-----------------	--

4.0 Product Information

Section F	Product Information
------------------	----------------------------

Common or classification name *

Assayed Quality Control Material

FDA Document Numbers of all prior related submissions (regardless of outcome) *

Item 1	N/A
--------	-----

4.1 Trade, Proprietary, or Model Names

Item: 1

Trade, proprietary, or model name for this device * Fujirebio Diagnostics Vitamin D Control

Model number * 2130152

5.0 Product Classification

Section G1	Product Classification
-------------------	-------------------------------

Choose the product code for this submission.

Product Code	SINGLE (SPECIFIED) ANALYTE CONTROLS (ASSAYED AND UNASSAYED) (JJX)
Device Class	CLASS I
Classification Panel	CLINICAL CHEMISTRY
C.F.R. Section	862.1660 - QUALITY CONTROL MATERIAL (ASSAYED AND UNASSAYED).

Add any other product codes that are applicable to this submission.

Item	Product Code	Device Class	Classification Panel	C.F.R. Section

If the product code(s) is/are unknown, please describe the classification of the product.

If necessary, identify the secondary Classification Panel

Item	
------	--

Section G2	Intended Use and Indications for Use
-------------------	---

<i>Information:</i>	<i>Intended use refers to "the objective intent of the persons legally responsible for the labeling of devices. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article..." (see 21 CFR 80 1.4).</i>
---------------------	---

[Code of Federal Regulations](#)

Enter the intended use of the product. *

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.

▪	Intended Use	
---	--------------	--

<i>Information:</i>	<i>For AST devices, the Indication For Use statement should indicate: whether the assay is quantitative (MIC) or qualitative (breakpoint devices); whether results may be read and reported manually; which organism groups the device is indicated for testing; and any instrumentation the device may be used with, if applicable. A typical example of an intended use statement is: "ABC's system is intended for the in vitro qualitative or quantitative determination of antimicrobial susceptibility of rapidly growing aerobic non-fastidious Gram positive and Gram negative organisms on the ABC Instrument."</i>
---------------------	--

[Code of Federal Regulations](#)

<i>Information:</i>	<i>Please attach the Indication(s) for Use Form to the following question.</i>
---------------------	--

[Indication\(s\) for Use Form](#)

Enter the product's 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.

File Attachment	Fujirebio Diagnostics Vitamin D Control IFU
-----------------	---

Enter any special applications of the device or contraindications not addressed in the Intended Use Statement.

6.0 Manufacturing/Packaging/Sterilization Sites

Item: 1

Status Change * No

Site Operation			
<input type="checkbox"/>	Manufacturer	*	Yes
<input type="checkbox"/>	Contract Manufacturer	*	No
<input type="checkbox"/>	Contract Sterilizer	*	No
<input type="checkbox"/>	Repackager/Relabeler	*	No

Contact Information	
<i>Contact Information:</i>	
Contact Name	Mr. John Gormley
Occupation Title	General Manager
Email Address	JGormley@fdi.com
<i>Establishment Information:</i>	
Establishment Name	Fujirebio Diagnostics, Inc.
Division Name	
FDA Establishment Identifier (FEI)	
Central File Number (CFN)	
Registration Number	1643621
Owner/Operator Number	(b)(4)
<i>Physical Location:</i>	
Address	940 Crossroads Blvd Seguin, TX, 78155, US
Telephone Number	(800) 531-7963
Fax Number	(830) 372-4130
<i>Mailing Location:</i>	
Address	940 Crossroads Blvd Seguin, TX, 78155, US

7.0 Utilization of Standards

Information: Select the CDRH Recognized Standard from the available list.

Select all standards referenced.

Item	Standard Title and Reference Number	Category	Organization
Item 1	Stability Testing of In Vitro Diagnostic Reagents (13640)(13640)	In Vitro	CEN

[Standards Data Report for 510\(k\)s \(FDA Form #3654, Form Approved OMB #0910-0120\)](#)

For each standard selected above, please fill out the Standards Data Report for 510(k)s (FDA Form #3654) and attach it here.

File Attachment	Fujiirebio Diagnostics Vitamin D Control Standards Form
Details	

Did you reference any other standards?	No
--	----

8.0 Utilization of Guidance Documents

Please enter all referenced Guidance Documents.				
Item	Document Title	Office	Division	Web Page
Item 1	Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material			http://www.fda.gov/cdrh/oivd/guidance/2231.html

9.0 Certification of Compliance with Clinical Trials

<i>Information:</i>	<i>The Food and Drug Administration has issued draft guidance titled: "Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions: Compliance with Section 402(j) of The Public Health Service Act, Added By Title VIII of The Food and Drug Administration Amendments Act of 2007".</i>
---------------------	---

The draft guidance can be found at: <http://www.fda.gov/RegulatoryInformation/Guidances/ucm125335.htm>
Form FDA-3674, ClinicalTrials.gov Data Bank

<i>Information:</i>	<i>Title VIII of the Food and Drug Administration Amendments Act of 2007 (FDAAA) included a provision that all MA applications are required to be accompanied with certification that all applicable clinical trial information has been submitted to the ClinicalTrials.gov data bank.</i>
	<i>Beginning December 26, 2007, submissions must include form FDA-3674. If your submission includes data from a clinical trial, you must determine if your study is applicable for entry into the clinical trial registry data bank at ClinicalTrials.gov.</i>

Form FDA-3674, ClinicalTrials.gov Data Bank

For each clinical trial, complete form FDA-3674 and attach it here.

File Attachment	Fujiirebio Diagnostics Vitamin D Clinical Trials Form
Details	

Section: OIVD Submission

OIVD 510(k)

OIVD 510(k) Submission

In vitro diagnostic (IVD) products are those reagents, instruments, and systems intended for use in diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body.

IVDs are medical devices as defined in section 210(h) of the Federal Food, Drug, and Cosmetic Act, and may also be biological products subject to section 351 of the Public Health Service Act. Like other medical devices, IVDs are subject to premarket and postmarket controls. IVDs are also subject to the Clinical Laboratory Improvement Amendments (CLIA '88) of 1988.

Is this an Antimicrobial Susceptibility Testing Device?	* No
---	------

Is this a Collection Device?	* No
------------------------------	------

Note: *The 510(k) Short Form is intended for experienced submitters who are familiar with the Turbo 510(k) program and the level of detail that is required when completing the submission.*

Would you like to complete the OIVD 510(k) Short Form?	* No
--	------

1.0 Type of Product

Please select one:	* Calibrators/Controls Only
--------------------	-----------------------------

Select Device Type:	
---------------------	--

Select device technology:	
---------------------------	--

Enter the device technology if you chose "Other."	

2.0 System Description

Information: *Please enter descriptions in executive summary format because this information will be used to generate the FDA Decision summary.*

Device Description

Enter a brief description of the characteristics of the device, i.e., physical design, components, etc. Include information on any specific accessories (e.g., specialized collection devices, materials for pre-analytical steps). *

Refer to attached file:	
Fujiirebio Diagnostics Vitamin D Control - Device Description	
File Attachment 1	Fujiirebio Diagnostics Vitamin D Control - Device Description
File Attachment 2	Fujiirebio Diagnostics Vitamin D Control - Substantial Equivalence

Is there an instrument associated with this assay?	* No
--	------

<ul style="list-style-type: none"> Has this instrument previously been deared? 	
---	--

<ul style="list-style-type: none"> Please enter the 510(k) number. 	
Item	

<ul style="list-style-type: none"> Have there been any modifications to the deared instrument for this particular assay? 	
---	--

<ul style="list-style-type: none"> Please describe the modification to the deared instrument. 	

Information: *The following questions relate to the Instrument.*

Modes of Operation
What are the modes of operation (i.e., random access, batch, stat, open tube, closed tube, automatic, manual, etc.)?

Software
What kind of software does the system use (i.e., operating system, user interface, data management, communications, laboratory information system, etc.)? Has the FDA reviewed the applicant's Hazard Analysis and software documentation for this line of product types?

Sample Identification
Describe how samples are identified (i.e., barcode, rack/position, instrument auto numbering, etc.).

Specimen Sampling and Handling
Describe how specimens are mixed (for whole blood), sampled, (i.e., direct open tube or closed tube piercing) and handled (i.e., manual, etc.).

Assay Types
What kinds of assays are run on the system (i.e., chemistry, immunoassay, cytochemistry, image analysis, Immunohistochemistry, etc.)?

Reaction Types
Describe what types of reactions the system is capable of measuring (i.e., photometric, fluorometric, nephelometric, turbidometric, etc.).

Calibration
Describe the calibration procedures for the system (i.e., use of whole blood and commercial calibration materials).

Quality Control
Describe the quality control procedures and the use of commercial quality control materials for Point-of-Care or home-use devices (i.e., handheld meters, describe any electronic QC procedures or process controls).

Other Supportive Performance Characteristics
Enter other supportive performance characteristics that were not covered in the Performance Characteristics section above. This information could include performance characteristics data unique to an instrument class in your division (i.e., flow cytometer, glucose meter, automated cell locating device, etc.).

Principles of Operation
Provide a description of the technology utilized in the device. Discuss the principles of the device methodology and indicate whether it is well established or new and unproven.

3.0 Substantial Equivalence Information

Item: 1

Note: *The predicate device drop-down is populated with the list created in Section 3.0 of the Admin Tab.*

Predicate device *

K043108 - 25(OH) Vitamin D Component of Bio-Rad Liquichek Specialty Immunoassay Control

Describe the item being compared *

Refer to attached file:

Fujirebio Diagnostics Vitamin D Control - Substantial Equivalence

File is attached in Section 2.0 - Device Description

Similarities *

Refer to attached file:

Fujirebio Diagnostics Vitamin D Control - Substantial Equivalence

File is attached in Section 2.0 - Device Description

Differences *

Refer to attached file:

Fujirebio Diagnostics Vitamin D Control - Substantial Equivalence

File is attached in Section 2.0 - Device Description

5.0 Performance Characteristics

Note: *Provide the information described below as appropriate to support the substantial equivalence determination. The type of data to be provided in this section depends on the intended use, technological characteristics of the new device, and claims.*

Note: *If you followed CLSI guidelines, which have specific instructions and calculations for determining performance, you may certify this instead of describing all the specifics of your protocol, statistical analyses, and line data. You should clarify which specific aspects of the protocol you followed, describe your deviations from the protocol, and describe any manufacturer-specific choices not specified in the guideline (e.g. number of lots or sites for precision or partitioning of sub-populations for reference range evaluation). You should also provide a summary of the results as listed below. CLSI guidelines relevant for the following sections include: EP5, Evaluation of Precision Performance of Clinical Chemistry Devices; EP12, User Protocol for Evaluation of Qualitative Test Performance; EP6, Evaluation of the Linearity of Quantitative Analytical Methods; EP7, Interference Testing in Clinical Chemistry; EP9, Method Comparison and Bias Estimation Using Patient Samples; EP14, Evaluation of Matrix Effects; GP10, Assessment of the Clinical Accuracy of Laboratory Tests Using Receiver Operating Characteristic (ROC) Plots; C28, How to Define and Determine Reference Intervals in the Clinical Laboratory; M2, Performance Standards for Antimicrobial Disk Susceptibility Tests; Approved Standard; M7, Methods for Dilution Antimicrobial Susceptibility Tests for Bacteria That Grow Aerobically; Approved Standard; M11, Methods for Antimicrobial Susceptibility Testing of Anaerobic Bacteria; Approved Standard; M23, Development of In Vitro Susceptibility Testing Criteria and Quality Control Parameters; Approved Guideline; M24, Susceptibility Testing of Mycobacteria, Nocardia, and Other Aerobic Actinomycetes; Approved Standard; M27, Reference Method for Broth Dilution Antifungal Susceptibility Testing of Yeasts; Approved Standard and M100, Performance Standards for Antimicrobial Susceptibility Testing; Fifteenth Informational Supplement.*

5.1 Analytical Performance

5.1.5 Traceability, Stability, Expected Values (Controls, Calibrators, Methods)

Where applicable, briefly summarize the following information about calibrators and controls: method and acceptance criteria for opened and closed stability studies, traceability to reference material, and description of value assignment, validation, and acceptance criteria. *

Stability - refer to attached file:

Fujirebio Diagnostics Vitamin D Control - Stability

Traceability - There are no claims made for traceability.

Value Assignment - refer to attached file:

Fujirebio Diagnostics Vitamin D Control - Value Assignment

Matrix Effects - refer to attached file:

Fujirebio Diagnostics Vitamin D Control - Matrix Effects

File Attachment 1	ARUP CAP Certification
File Attachment 2	ARUP CLIA Certification
File Attachment 3	DiaSorin ISO 9001 Certification
File Attachment 4	DiaSorin ISO 13485 Certification
File Attachment 5	FDI ISO 9001 Certification
File Attachment 6	FDI ISO 13485 Certification
File Attachment 7	(b)(4)
File Attachment 8	
File Attachment 9	
File Attachment 10	

5.1.8 Instrument Only

Accuracy

Compare each test parameter to either a reference method or a predicate device with the same intended use. Use a testing pool that contains samples representative of the appropriate population. Include an equal number of males and females for which samples span the reportable range. Include specimens that are close to the clinically critical decision point(s). Present the data using linear regression, including 95% confidence intervals for the slope and y-intercept. Provide scatter plots.

Precision/Reproductibility

Provide estimates of intra, inter, lot-to-lot, operator-to-operator, and total imprecision for each measurand parameter of the device using samples that span the testing range.

Linearity

Provide information on how linearity was established and indicate whether this conformed to EP6-PS or any other appropriate methodology.

Carryover

Provide studies to demonstrate lack of over estimation of results due to the carryover effect. The testing pool should consist of samples at clinically meaningful levels.

--

Interfering Substances

Provide studies to show possible interference of substances such as lipids, hemoglobin, bilirubin, etc.

6.0 Labeling

Provide proposed package labeling to demonstrate conformance to 21 CFR 809.10. Also, include package insert for the predicate device, if available. Labeling at a minimum should include: device components and specifications, reagent composition and important specifications, precautions/warnings, limitations, storage requirements, specimen handling and storage requirements, expiration/stability dating, instructions for reconstitution, mixing, and dilution, assay procedure, calibration, quality controls, results (calculations, formulas), results(interpretation), performance characteristics (summarize reproducibility, etc.), and study design (population studied, N, type of sample, matrix, dilution, target concentrations, etc.).	*
---	---

Refer to attached files:								
(b)(4)								
<table border="1"> <tr> <td>File Attachment 1</td> <td rowspan="7" style="text-align: center; vertical-align: middle;">(b)(4)</td> </tr> <tr> <td>File Attachment 2</td> </tr> <tr> <td>File Attachment 3</td> </tr> <tr> <td>File Attachment 4</td> </tr> <tr> <td>File Attachment 5</td> </tr> <tr> <td>File Attachment 6</td> </tr> <tr> <td>File Attachment 7</td> </tr> </table>	File Attachment 1	(b)(4)	File Attachment 2	File Attachment 3	File Attachment 4	File Attachment 5	File Attachment 6	File Attachment 7
File Attachment 1	(b)(4)							
File Attachment 2								
File Attachment 3								
File Attachment 4								
File Attachment 5								
File Attachment 6								
File Attachment 7								

Note:	<i>The minimum requirements above do not include requirements for instruments. Additional labeling recommendations may apply to Class II devices with special controls and Guidance.</i>
-------	--

7.0 Other Supportive Information

Enter any additional supporting information for this submission such as: manufacturing information for critical reagents, copies of bibliography references, financial disclosures, and software validation or certification statements, if necessary to support equivalence.	*
N/A	

The College of American Pathologists

certifies that the laboratory named below

ARUP Laboratories, Inc
Salt Lake City, Utah
Sherrie L. Perkins, MD, PhD

LAP Number: 4096301
AU-ID: 1190252
CLIA Number: 46D0523979

has met all applicable standards for accreditation and is hereby fully accredited by the College of American Pathologists' Laboratory Accreditation Program. Reinspection should occur prior to November 20, 2011 to maintain accreditation.

Accreditation does not automatically survive a change in director, ownership, or location and assumes that all interim requirements are met.

Frank R Rudy

Chair, Commission on Laboratory Accreditation

Stephen H Bean MD FACP

President, College of American Pathologists



Advancing Excellence

Accredited Laboratory



**CENTERS FOR MEDICARE & MEDICAID SERVICES
CLINICAL LABORATORY IMPROVEMENT AMENDMENTS
CERTIFICATE OF ACCREDITATION**

LABORATORY NAME AND ADDRESS

ASSOCIATED REGIONAL & UNIVERSITY PATHO
500 CHIPETA WAY
SALT LAKE CITY, UT 84108-1221

CLIA ID NUMBER

46D0523979

EFFECTIVE DATE

02/09/2009

LABORATORY DIRECTOR

EDWARD R ASHWOOD MD

EXPIRATION DATE

02/08/2011

Pursuant to Section 353 of the Public Health Services Act (42 U.S.C. 263a) as revised by the Clinical Laboratory Improvement Amendments (CLIA), the above named laboratory located at the address shown hereon (and other approved locations) may accept human specimens for the purposes of performing laboratory examinations or procedures.

This certificate shall be valid until the expiration date above, but is subject to revocation, suspension, limitation, or other sanctions for violation of the Act or the regulations promulgated thereunder.



Judith A. Yost

Judith A. Yost, Director
Division of Laboratory Services
Survey and Certification Group
Center for Medicaid and State Operations

1013 certs2_011009

If you currently hold a Certificate of Compliance or Certificate of Accreditation, below is a list of the laboratory specialties/subspecialties you are certified to perform and their effective date:

<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>	<u>LAB CERTIFICATION (CODE)</u>	<u>EFFECTIVE DATE</u>
HISTOCOMPATIBILITY (010)	10/28/1999	ANTIBODY TRANSFUSION (520)	10/13/1995
BACTERIOLOGY (110)	10/13/1995	ANTIBODY NON-TRANSFUSION (530)	10/13/1995
MYCOBACTERIOLOGY (115)	10/13/1995	ANTIBODY IDENTIFICATION (540)	10/13/1995
MYCOLOGY (120)	10/13/1995	HISTOPATHOLOGY (610)	04/10/2007
PARASITOLOGY (130)	10/13/1995	CYTOLOGY (630)	06/13/2003
VIROLOGY (140)	10/13/1995	CYTOGENETICS (900)	09/30/2003
SYPHILIS SEROLOGY (210)	10/13/1995		
GENERAL IMMUNOLOGY (220)	10/13/1995		
ROUTINE CHEMISTRY (310)	10/13/1995		
ENDOCRINOLOGY (330)	10/13/1995		
TOXICOLOGY (340)	10/13/1995		
HEMATOLOGY (400)	10/13/1995		
ABO & RH GROUP (510)	10/13/1995		

FOR MORE INFORMATION ABOUT CLIA, VISIT OUR WEBSITE AT WWW.CMS.HHS.GOV/CLIA
OR CONTACT YOUR LOCAL STATE AGENCY. PLEASE SEE THE REVERSE FOR
YOUR STATE AGENCY'S ADDRESS AND PHONE NUMBER.
PLEASE CONTACT YOUR STATE AGENCY FOR ANY CHANGES TO YOUR CURRENT CERTIFICATE.
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or 301-796-8118



Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485: 2003

COPY

This is to certify that:

DiaSorin, Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater
Minnesota
55082
USA

Holds Certificate No: **FM 74610**

and operates a Quality Management System which complies with the requirements of ISO 13485: 2003 for the following scope:

The design/development, manufacture, service and distribution of in-vitro diagnostic devices and analyzers for the diagnosis and management of infectious diseases and cancer, therapeutic drug monitoring, bone mineral and serum protein metabolism and endocrine and autoimmune disorders for the medical care and research related industries.

For and on behalf of BSI:

President, BSI America, Inc.

Originally Registered: **12/27/2002**

Effective Date: **11/06/2009**

Expiry Date: **11/05/2012**



CMDCAS
Recognized
Registrar

Page: 1 of 1

This certificate remains the property of BSI and shall be returned immediately upon request. An electronic certificate can be authenticated [online](#). Printed copies can be validated at www.bsigroup.com/ClientDirectory To be read in conjunction with the scope above or the attached appendix.
Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.





Certificate of Registration

COPY

QUALITY MANAGEMENT SYSTEM - ISO 9001:2008

This is to certify that:

DiaSorin, Inc.
1951 Northwestern Avenue
P.O. Box 285
Stillwater
Minnesota
55082
USA

Holds Certificate No: **FM 65867**

and operates a Quality Management System which complies with the requirements of ISO 9001:2008 for the following scope:

The design/development, manufacture, service and distribution of in-vitro diagnostic devices and analyzers for the diagnosis and management of infectious diseases and cancer, therapeutic drug monitoring, bone mineral and serum protein metabolism and endocrine and autoimmune disorders for the medical care and research related industries.

For and on behalf of BSI:

President, BSI America, Inc.

Originally Registered: **07/09/1997**

Latest Issue: **10/27/2009**

Expiry Date: **11/07/2012**



Page: 1 of 1

This certificate remains the property of BSI and shall be returned immediately upon request.
An electronic certificate can be authenticated [online](http://www.bsigroup.com/ClientDirectory). Printed copies can be validated at www.bsigroup.com/ClientDirectory
To be read in conjunction with the scope above or the attached appendix.
Americas Headquarters: 12110 Sunset Hills Road, Suite 200, Reston, VA 20190, USA.





CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

**Fujirebio Diagnostics, Inc.
Malvern, Pennsylvania, USA**

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

ISO 13485:2003

The Quality Management System is applicable to:

**Design and Manufacture of In Vitro
Diagnostic and Research Products.**

Approval
Certificate No: UQA 0112325/C

Original Approval: May 4, 2001

Current Certificate: June 1, 2007

Certificate Expiry: May 31, 2010

Issued by: LRQA, Inc. Houston



001

This document is subject to the provision on the reverse
1401 Enclave Parkway, Suite 200, Houston Texas 77077 USA

This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.
The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001

Macro Revision 13



CERTIFICATE OF APPROVAL

This is to certify that the Quality Management System of:

**Fujirebio Diagnostics, Inc.
Malvern, Pennsylvania, USA**

has been approved by Lloyd's Register Quality Assurance
to the following Quality Management System Standards:

**ISO 9001:2000
ANSI/ISO/ASQ Q9001-2000**

The Quality Management System is applicable to:

**Design and Manufacture of In Vitro
Diagnostic and Research Products.**

Approval
Certificate No: UQA 0112325/A

Original Approval: May 4, 2001

Current Certificate: June 1, 2007

Certificate Expiry: May 31, 2010

Issued by: LRQA, Inc. Houston



001

This document is subject to the provision on the reverse

1401 Enclave Parkway, Suite 200, Houston Texas 77077 USA

This approval is carried out in accordance with the LRQA assessment and certification procedures and monitored by LRQA.

The use of the UKAS Accreditation Mark indicates Accreditation in respect of those activities covered by the Accreditation Certificate Number 001

Macro Revision 13



DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Certification of Compliance, under 42 U.S.C. § 282(j)(5)(B), with Requirements of ClinicalTrials.gov Data Bank (42 U.S.C. § 282(j))

(For submission with an application/submission, including amendments, supplements, and resubmissions, under §§ 505, 515, 520(m), or 510(k) of the Federal Food, Drug, and Cosmetic Act or § 351 of the Public Health Service Act.)

SPONSOR / APPLICANT / SUBMITTER INFORMATION

1. NAME OF SPONSOR/APPLICANT/SUBMITTER Fujirebio Diagnostics Inc.	2. DATE OF THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES March 2, 2011
3. ADDRESS (Number, Street, State, and ZIP Code) 940 Crossroads Blvd. Seguin, TX 78155	4. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 1-800-531-7963 (Fax) 830-372-4130

PRODUCT INFORMATION

5. **FOR DRUGS/BIOLOGICS:** Include Any/All Available Established, Proprietary and/or Chemical/Biochemical/Blood/Cellular/Gene Therapy Product Name(s)
FOR DEVICES: Include Any/All Common or Usual Name(s), Classification, Trade or Proprietary or Model Name(s) and/or Model Number(s)
(Attach extra pages as necessary)

Single (Specified) analyte controls, (Assayed and Unassayed) - JJX

Class I

Fujirebio Diagnostics Vitamin D Control

2130152

APPLICATION / SUBMISSION INFORMATION

6. TYPE OF APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

IND NDA ANDA BLA PMA HDE 510(k) PDP Other

7. INCLUDE IND/NDA/ANDA/BLA/PMA/HDE/510(k)/PDP/OTHER NUMBER (If number previously assigned)

8. SERIAL NUMBER ASSIGNED TO APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES

CERTIFICATION STATEMENT / INFORMATION

9. CHECK ONLY ONE OF THE FOLLOWING BOXES (See instructions for additional information and explanation)

A. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply because the application/submission which this certification accompanies does not reference any clinical trial.

B. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, do not apply to any clinical trial referenced in the application/submission which this certification accompanies.

C. I certify that the requirements of 42 U.S.C. § 282(j), Section 402(j) of the Public Health Service Act, enacted by 121 Stat. 823, Public Law 110-85, apply to one or more of the clinical trials referenced in the application/submission which this certification accompanies and that those requirements have been met.

10. IF YOU CHECKED BOX C, IN NUMBER 9, PROVIDE THE NATIONAL CLINICAL TRIAL (NCT) NUMBER(S) FOR ANY "APPLICABLE CLINICAL TRIAL(S)," UNDER 42 U.S.C. § 282(j)(1)(A)(i), SECTION 402(j)(1)(A)(i) OF THE PUBLIC HEALTH SERVICE ACT, REFERENCED IN THE APPLICATION/SUBMISSION WHICH THIS CERTIFICATION ACCOMPANIES (Attach extra pages as necessary)

NCT Number(s):

The undersigned declares, to the best of her/his knowledge, that this is an accurate, true, and complete submission of information. I understand that the failure to submit the certification required by 42 U.S.C. § 282(j)(5)(B), section 402(j)(5)(B) of the Public Health Service Act, and the knowing submission of a false certification under such section are prohibited acts under 21 U.S.C. § 331, section 301 of the Federal Food, Drug, and Cosmetic Act.
Warning: A willfully and knowingly false statement is a criminal offense, U.S. Code, title 18, section 1001.

11. SIGNATURE OF SPONSOR/APPLICANT/SUBMITTER OR AN AUTHORIZED REPRESENTATIVE (Sign) 	12. NAME AND TITLE OF THE PERSON WHO SIGNED IN NO. 11 (Name) Diana Dickson (Title) Manager, Regulatory Affairs
13. ADDRESS (Number, Street, State, and ZIP Code) (of person identified in Nos. 11 and 12) 201 Great Valley Parkway Malvern, PA 19355	14. TELEPHONE AND FAX NUMBERS (Include Area Code) (Tel.) 610-240-3917 (Fax) 610-240-3803
15. DATE OF CERTIFICATION March 2, 2011	

Premarket Notification (510(k))
Tumor Marker Control



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
dolans@fdi.com

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.

Premarket Notification (510(k))
Tumor Marker Control



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	<i>In vitro</i> diagnostic	<i>In vitro</i> 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

Premarket Notification (510(k))
Tumor Marker Control



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

FDI

(b)(4)

(b)(4)

CONFIDENTIAL

(b)(4)

FDI

(b)(4)

TEAM

FDI	(b)(4)	(b)(4) CONFIDENTIAL
------------	--------	-------------------------------

Author's Signature:

Your signature indicates that this document has been prepared in accordance with existing project standards and adequately describes the experimental rationale, protocol, its results and conclusions.

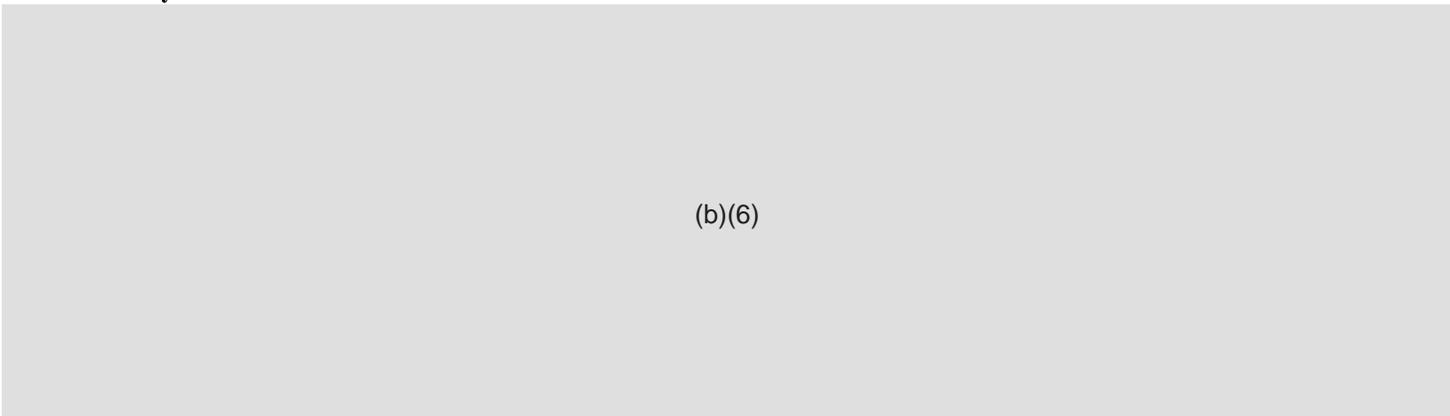
Authored By:

John Gormley General Manager		<i>20 Feb 11</i>	FDI (Seguin)
Typed/Printed Name, Title	Signature	Date	Unit

Reviewers' Signatures:

Your signature indicates that, you have reviewed this document and that it accurately and completely describes the experimental rationale, protocol, its results and conclusions.

Reviewed By:

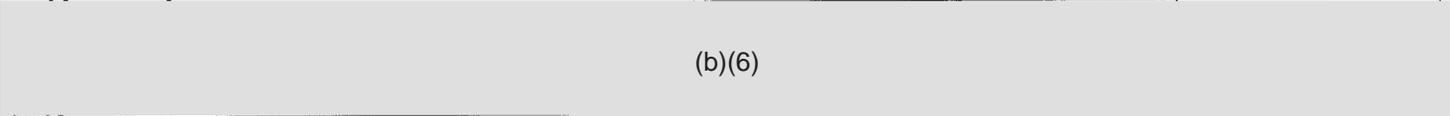


(b)(6)

Quality Control/Compliance Approver's Signature:

Your signature indicates that this document complies with applicable regulatory, corporate, divisional/departmental requirements, and current Quality System Regulations.

Approved By:



(b)(6)

FDI (b)(4) TEAM

FDI	(b)(4)	Page 2 of 10 (b)(4) CONFIDENTIAL
------------	--------	---

Author's Signature:

Your signature indicates that this document has been prepared in accordance with existing project standards and adequately describes the experimental rationale, protocol, its results and conclusions.

Authored By:

John Gormley General Manager			FDI (Seguin)
Typed/Printed Name, Title	Signature	Date	Unit

Reviewers' Signatures:

Your signature indicates that, you have reviewed this document and that it accurately and completely describes the experimental rationale, protocol, its results and conclusions.

Reviewed By:

(b)(6)

Quality Control/Compliance Approver's Signature:

Your signature indicates that this document complies with applicable regulatory, corporate, divisional/departmental requirements, and current Quality System Regulations.

Approved By:

(b)(6)

FDI (b)(4) TEAM

FDI	(b)(4)	(b)(4) CONFIDENTIAL
------------	--------	-------------------------------

Revision History

Revision	Effective Date	Revision: Reason for Revision	Revised By
Original	30 SEP 10	Establish Plan	N/A
(b)(4)			J. Gormley
			J. Gormley

FDI

(b)(4)

TEAM

FDI	(b)(4)	(b)(4) CONFIDENTIAL
------------	--------	-------------------------------

TABLE OF CONTENTS

1. INTRODUCTION5

1.1 PURPOSE.....5

1.2 POLICY COMPLIANCE5

1.3 SCOPE.....5

1.4 DEFINITIONS5

2. REGULATORY REQUIREMENTS.....5

3. OVERVIEW6

3.1 PRE-VALIDATION DATA.....6

3.2 INITIAL VALIDATION EFFORT6

3.3 VALIDATION APPROACH6

4. RESOURCES.....6

4.1 PERSONNEL RESPONSIBILITIES6

4.2 MATERIALS USED.....7

5. VALIDATION PROCEDURE7

5.1 SAMPLE PREPARATION7

5.2 ASSAY PROCEDURE8

5.3 DATA ANALYSIS.....8

6. RESULTS.....8

6.1 ASSAY VALIDITY.....8

6.2 DATA.....8

6.3 CORRELATION9

7. DISCUSSION/CONCLUSION.....9

8. REFERENCES9

9. ATTACHMENTS.....10

FDI	(b)(4)	TEAM
-----	--------	------

FDI

(b)(4)

(b)(4)

CONFIDENTIAL

1. Introduction

1.1 Purpose

The purpose of this report is to document and conclude whether the Vitamin D Multi-Level Serum Controls behave as patient samples when assayed using a typical in vitro diagnostic product for Vitamin D.

1.2 Policy Compliance

This document is being written to comply with corporate policy requirements as stated in

(b)(4)

1.3 Scope

This report is limited to the Vitamin D Multi-Level Serum Controls Kit Cat. No.: 2130152.

1.4 Definitions

Limit of Detection (LOD) – The lowest quantity that can be differentiated from zero. The LOD for the Diasorin 25-Hydroxyvitamin D ¹²⁵I RIA kit is published at 1.5 ng/mL.

Malvern – Fujirebio Diagnostics, Inc., Malvern PA

Matrix – All components of a material system, except the analyte.

Matrix Effect – The influence of a property of the sample, other than the analyte, on the measurement, and thereby on the value of the measurable quantity.

Seguin – Fujirebio Diagnostics, Inc., Seguin TX

2. Regulatory Requirements

The FDA guidance document Center for Devices and Radiological Health Staff. (June 7, 2007). Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material #223 Section IV.B.1 states that matrix effects present:

...a potential risk to health since QC material is the best source of ongoing “feedback” a laboratory has to monitor whether results reported to physicians are sufficiently accurate. Therefore, we recommend that you evaluate matrix effects of your QC material relative to the intended use human samples and describe relevant findings in the package insert.

Another related issue is that as a result of differences in matrices, QC materials might differ from patient samples in terms of preparatory steps required for the assay (e.g., dilution, extraction, centrifugation or other pre-treatment). We recommend that, whenever feasible, you design the QC material so that it may monitor performance of preparatory steps as well as the operational steps of the assay itself. If this is not the case, you should indicate to users in the package insert which operational steps of the assay the QC material might not be able to monitor.

FDI

(b)(4)

TEAM

FDI	(b)(4)	(b)(4) CONFIDENTIAL
------------	--------	-------------------------------

3. Overview

3.1 Pre-validation Data

(b)(4)

3.2 Initial Validation Effort

(b)(4)

3.3 Validation Approach

(b)(4)

4. Resources

4.1 Personnel Responsibilities

(b)(4)

FDI PRODUCT REVIEW TEAM

FDI	(b)(4)	(b)(4) CONFIDENTIAL
------------	--------	-------------------------------

4.2 Materials Used

(b)(4)

5. Validation Procedure

5.1 Sample Preparation

(b)(4)

FDI (b)(4) TEAM

FDI	(b)(4)	(b)(4) CONFIDENTIAL
------------	--------	-------------------------------

5.2 Assay Procedure

(b)(4)

5.3 Data Analysis

(b)(4)

6. Results

6.1 Assay Validity

(b)(4)

6.2 Data

The table below shows the assay results:

(b)(4)

FDI	(b)(4)	TEAM
-----	--------	------

FDI	(b)(4)	(b)(4) CONFIDENTIAL
------------	--------	-------------------------------

(b)(4)

6.3 Correlation

(b)(4)

7. Discussion/Conclusion

(b)(4)

8. References

- Food and Drug Administration, Center for Devices and Radiological Health Staff. (June 7, 2007). *Guidance for Industry and FDA Staff - Assayed and Unassayed Quality Control Material #223.*
- (b)(4)
- REF: 68100E Diasorin 25-Hydroxyvitamin D ¹²⁵I RIA Kit Instruction Manual
- (b)(4)

FDI (b)(4) TEAM

FDI

(b)(4)

(b)(4)

CONFIDENTIAL

9. Attachments

- Attachment 1 Patient Sample Listing 6 pages
- Attachment 2 Initial Regression Results 3 pages
- Attachment 3 Regression with Repeated Sample 3 pages

FDI

(b)(4)

TEAM

Pages 45 through 56 redacted for the following reasons:

Test Data: (b)(4)-Trade Secret

Test Data: (b)(4)-Trade Secret

Patient Identifiers-(b)(6)-Personal Privacy Information

Premarket Notification (510(k))
Vitamin D Control



DEVICE DESCRIPTION

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.

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.

Composition:

(b)(4)

Premarket Notification (510(k))
Vitamin D Control



Storage and Stability

Unopened:

- This product is stable until the expiration date when stored unopened at 2-8°C.

Reconstituted:

- Once the control is reconstituted, the product is stable for 14 days when stored tightly capped at 2-8 °C.
- The product is stable for 60 days when stored at ≤ -10 °C.
- Controls may be frozen and thawed repeatedly for up to 9 cycles.

Safety Information

(b)(4)

Premarket Notification (510(k))
Vitamin D Control



MATRIX EFFECTS

Fujirebio Diagnostics Vitamin D Control is prepared from human serum, protein (bovine), purified biochemical materials, and chemicals. It also contains Proclin 300® and Gentamicin as preservatives. In order to ensure these various additives do not compromise Fujirebio Diagnostics Vitamin D Control's ability to sufficiently reflect performance of the assay for "natural" human samples a study was conducted.

Refer to Attached Vitamin D Controls Matrix Effects Report.

Premarket Notification (510(k))
Vitamin D Control



STABILITY STUDIES

Several studies were conducted to evaluate the stability of the Fujirebio Diagnostics Vitamin D Control Kits.

The stability studies were performed in compliance to the EN standard, 13640 – Stability Testing of *In Vitro* Diagnostic Reagents.

(b)(4)

Results

Pages 61 through 63 redacted for the following reasons:

Test Data: (b)(4)-Trade Secret

Premarket Notification (510(k))
Vitamin D Control



Conclusion

(b)(4)

This study supports the proposed product insert statement:

Once the control is reconstituted, the product is stable for 14 days when stored tightly capped at 2-8°C.

Pages 65 through 72 redacted for the following reasons:

Test Data: (b)(4)-Trade Secret



ASSIGNED VALUES SHEET

REF 2130152 **LOT** 307995  **EXP** 2011-08

ANALYTES	ASSAY UNIT	LEVEL 1			SI UNIT	LEVEL 1		
		Mean	Range	% Uncertainty		Mean	Range	% Uncertainty
VITAMIN D								
DiaSorin LIAISON	ng/mL	10.9	7.0-14.9	4.9	nmol/L	27.2	17.5-37.2	4.9
DiaSorin RIA	ng/mL	11.6	7.4-15.8	5.7	nmol/L	29.0	18.5-39.4	5.7
IDS EIA	ng/mL	8.4	5.9-10.9	1.7	nmol/L	21.0	14.7-27.3	1.7
LC-MS/MS	ng/mL	12.8	8.9-16.6	2.4	nmol/L	31.9	22.2-41.4	2.4
ANALYTES	ASSAY UNIT	LEVEL 2			SI UNIT	LEVEL 2		
		Mean	Range	% Uncertainty		Mean	Range	% Uncertainty
VITAMIN D								
DiaSorin LIAISON	ng/mL	32.0	22.4-41.7	3.4	nmol/L	79.9	55.9-104.1	3.4
DiaSorin RIA	ng/mL	31.0	19.8-42.2	3.6	nmol/L	77.4	49.4-105.3	3.6
IDS EIA	ng/mL	16.6	11.6-21.6	1.1	nmol/L	41.5	29.0-53.9	1.1
LC-MS/MS	ng/mL	29.8	20.8-38.7	2.1	nmol/L	74.4	51.9-96.6	2.1
ANALYTES	ASSAY UNIT	LEVEL 3			SI UNIT	LEVEL 3		
		Mean	Range	% Uncertainty		Mean	Range	% Uncertainty
VITAMIN D								
DiaSorin LIAISON	ng/mL	74.3	56.5-92.1	2.8	nmol/L	185	141-230	2.8
DiaSorin RIA	ng/mL	68.7	43.9-93.5	5.0	nmol/L	171	110-233	5.0
IDS EIA	ng/mL	32.8	23.0-42.5	1.7	nmol/L	81.9	57.3-106	1.7
LC-MS/MS	ng/mL	72.4	50.7-94.2	1.7	nmol/L	181	127-235	1.7



Updates of assigned values will be available on www.fdi.com

Fujirebio Diagnostics, Inc.
 940 Crossroads Blvd.
 Seguin, Texas 78155
 USA
 Phone + 1-830-372-1391
 + 1-800-531-7963
 Fax + 1-830-372-4130
customerservice@fdi.com
www.fdi.com



Fujirebio Diagnostics, AB
 Elof Lindälvs gata 13
 SE-414 55 Göteborg
 Sweden
 Phone + 46 31 85 70 30
 Fax + 46 31 85 70 40
info@fdab.com
www.fdadab.com



093119.00 REV.000



Vitamin D CONTROL

REF 2130152 LOT

CONT

Control, Level 1 2 x 2 mL

Control, Level 2 2 x 2 mL

Control, Level 3 2 x 2 mL


 Fujirebio Diagnostics, Inc.
 940 Crossroads Blvd.
 Seguin, TX 78155
 USA

+1-830-372-1391 phone
 1-800-531-7963 phone
 +1-830-372-4130 fax
 customerservice@FDL.com
 www.FDL.com


 IVD CE

093072.00 Rev.000

Product Information	Specified Colors	Proof C	Date: 10/27/10																														
<p>P/N: 093072-00Rev000 J/N: 190337 Cust.: Fujirebio Size: 3.3125x2.125 Die#: 0984D-L-12 CR: .0625 Die Line Does Not Print</p>	<table border="1" style="width: 100%; text-align: center;"> <tr> <td style="background-color: black; width: 20px; height: 20px;"></td> <td style="background-color: cyan; width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> <td style="background-color: black; width: 20px; height: 20px;"></td> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="font-size: 8px;">Black</td> <td style="font-size: 8px;">Die</td> <td style="font-size: 8px;">Overall Varnish</td> <td style="font-size: 8px;">UV Black</td> <td></td> </tr> </table> <table border="1" style="width: 100%; text-align: center;"> <tr> <td style="background-color: black; width: 20px; height: 20px;"></td> <td style="background-color: cyan; width: 20px; height: 20px;"></td> <td style="background-color: magenta; width: 20px; height: 20px;"></td> <td style="background-color: yellow; width: 20px; height: 20px;"></td> </tr> <tr> <td style="font-size: 8px;">K</td> <td style="font-size: 8px;">C</td> <td style="font-size: 8px;">M</td> <td style="font-size: 8px;">Y</td> </tr> <tr> <td colspan="4" style="font-size: 8px;">Indichrome Plus (+)</td> </tr> <tr> <td style="width: 20px; height: 20px;"></td> </tr> <tr> <td style="font-size: 8px;">O</td> <td style="font-size: 8px;">G</td> <td style="font-size: 8px;">V</td> <td></td> </tr> </table>						Black	Die	Overall Varnish	UV Black						K	C	M	Y	Indichrome Plus (+)								O	G	V		<p>Approved By</p> <p>Customer: _____</p> <p>Date: _____</p> <p style="font-size: 8px;">Note: We must have a signed proof before we can begin production.</p> <p> <input type="checkbox"/> OK to print <input type="checkbox"/> Another proof required <input type="checkbox"/> See Attached </p>	
Black	Die	Overall Varnish	UV Black																														
K	C	M	Y																														
Indichrome Plus (+)																																	
O	G	V																															
<p>Note: This proof is to show size, copy and color breaks. <input type="checkbox"/> This proof is color correct.</p> <p>Color: Actual colors will be matched on press to: <input type="checkbox"/> This proof contains braille.</p> <p style="font-size: 8px;">PMS Book, On_Demand Solutions Four Color Book, On_Demand Solutions Indichrome Plus Color Book and/or approved Color Standards</p>		<div style="background-color: #0056b3; color: white; padding: 5px; text-align: center;"> Nosco® Item Level SerializationSM </div>  <div style="background-color: #0056b3; color: white; padding: 5px; text-align: center;">  <p style="font-size: 8px;">For more information visit http://www2.nosco.com/ILS/</p> </div>																															
<div style="background-color: #0056b3; color: white; padding: 5px; text-align: center;"> complete packaging individual solutionsSM Nosco makes it easier... </div> 		651 S ML King Jr Ave • Waukegan, IL 60085 Phone (847) 336-4200 • FAX (847) 360-4924																															

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)

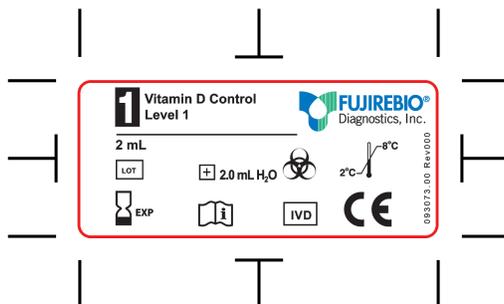
(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

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

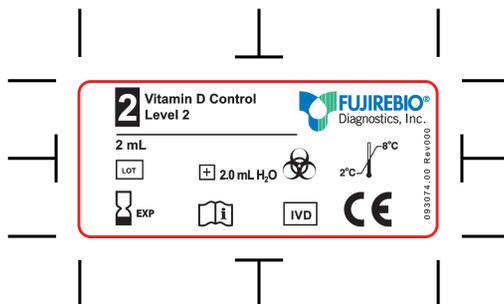
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) _____

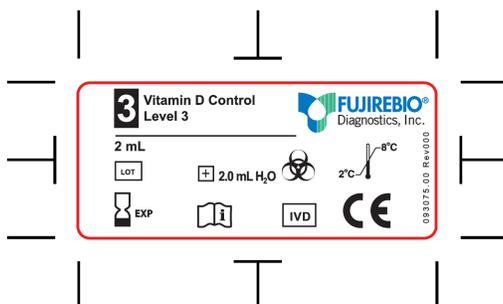
Page 1 of ____



Product Information		Specified Colors		Proof C		Date: 12/15/10																											
P/N: 093073.00Rev000 J/N: 190338 Cust.: Fujirebio Size: 1.875 X 0.8125 Die#: NA CR: .0625 Die Line Does Not Print		<table border="1"> <tr> <td>Black</td> <td>300</td> <td>340</td> <td>Dieline</td> <td>Overall Varnish</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>		Black	300	340	Dieline	Overall Varnish						<table border="1"> <tr> <td>K</td> <td>C</td> <td>M</td> <td>Y</td> </tr> <tr> <td colspan="4">Indichrome Plus (+)</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>O</td> <td>G</td> <td>V</td> <td>W</td> </tr> </table>		K	C	M	Y	Indichrome Plus (+)								O	G	V	W	Approved By Customer: _____ Date: _____ Note: We must have a signed proof before we can begin production.	
Black	300	340	Dieline	Overall Varnish																													
K	C	M	Y																														
Indichrome Plus (+)																																	
O	G	V	W																														
Note: This proof is to show size, copy and color breaks. <input type="checkbox"/> This proof is color correct. Color: Actual colors will be matched on press to: <input type="checkbox"/> This proof contains braille. PMS Book, On_Demand Solutions Four Color Book, On_Demand Solutions Indichrome Plus Color Book and/or approved Color Standards		<input type="checkbox"/> OK to print <input type="checkbox"/> See Attached		<input type="checkbox"/> Another proof required																													
<p style="text-align: center;">complete packaging individual solutionsSM Nosco makes it easier...</p>  <p style="text-align: center;">651 S ML King Jr Ave • Waukegan, IL 60085 Phone (847) 336-4200 • FAX (847) 360-4924</p>				<p style="text-align: center;">Nosco® Item Level SerializationSM</p>   <p style="text-align: center;">For more information visit http://www2.nosco.com/ILS/</p>																													



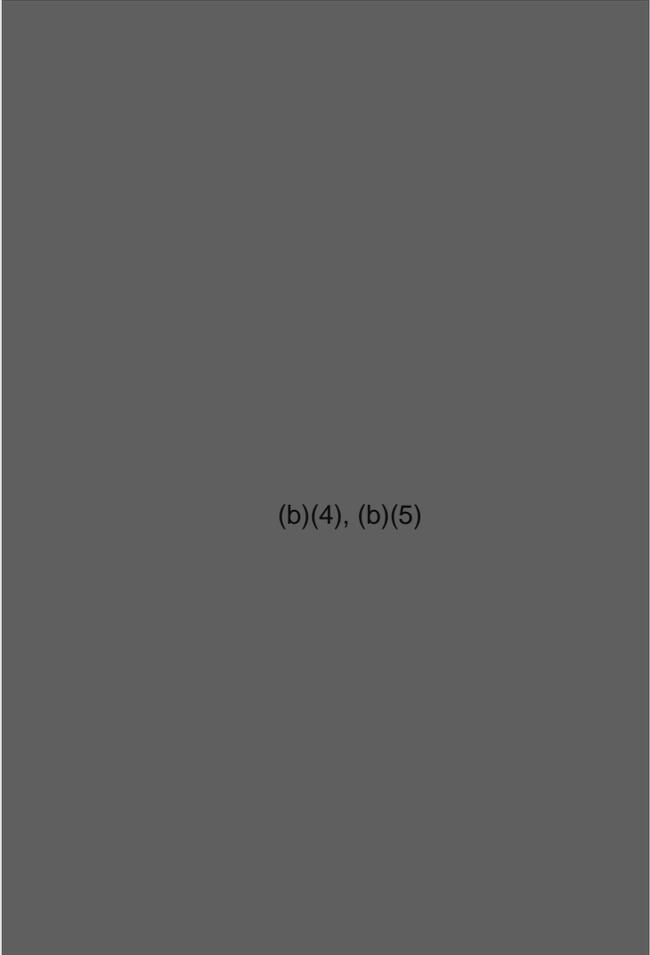
Product Information		Specified Colors		Proof B		Date: 10/25/10																																
P/N: 093074-00Rev000 J/N: 190189 Cust.: Fujirebio Size: 1.875 X 0.8125 Die#: NA CR: .0625 Die Line Does Not Print		<table border="1"> <tr> <td>Black</td> <td>300</td> <td>340</td> <td>Dieline</td> <td>Overall Varnish</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>		Black	300	340	Dieline	Overall Varnish											<table border="1"> <tr> <td>K</td> <td>C</td> <td>M</td> <td>Y</td> </tr> <tr> <td colspan="4">Indichrome Plus (+)</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>O</td> <td>G</td> <td>V</td> <td>W</td> </tr> </table>		K	C	M	Y	Indichrome Plus (+)								O	G	V	W	Approved By Customer: _____ Date: _____ Note: We must have a signed proof before we can begin production.	
Black	300	340	Dieline	Overall Varnish																																		
K	C	M	Y																																			
Indichrome Plus (+)																																						
O	G	V	W																																			
Note: This proof is to show size, copy and color breaks. <input type="checkbox"/> This proof is color correct. Color: Actual colors will be matched on press to: PMS Book, On_Demand Solutions Four Color Book, On_Demand Solutions Indichrome Plus Color Book and/or approved Color Standards <input type="checkbox"/> This proof contains braille.		<input type="checkbox"/> OK to print <input type="checkbox"/> See Attached		<input type="checkbox"/> Another proof required																																		
<p style="text-align: center;">complete packaging individual solutionsSM Nosco makes it easier...</p>  <p style="text-align: center;">651 S ML King Jr Ave • Waukegan, IL 60085 Phone (847) 336-4200 • FAX (847) 360-4924</p>				 <p style="text-align: center;">For more information visit http://www2.nosco.com/securityprotection/</p>																																		



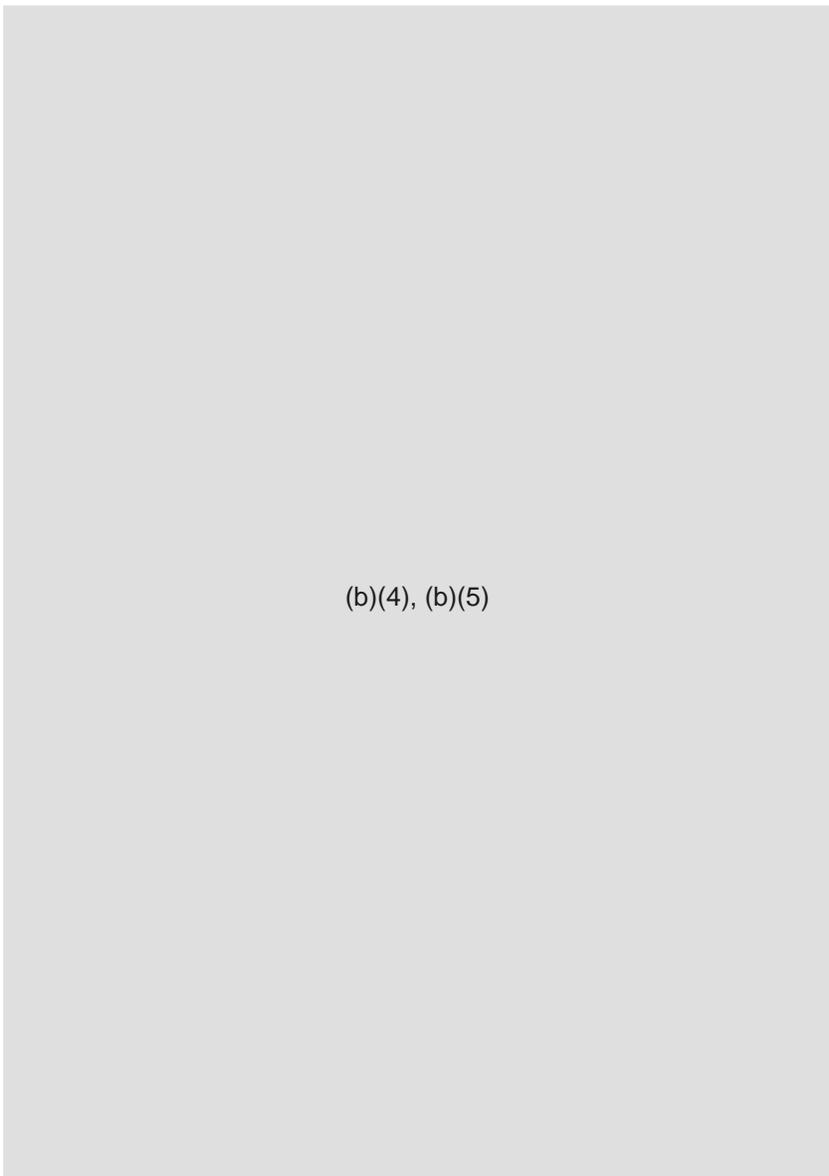
Product Information		Specified Colors		Proof B		Date: 10/25/10																																
P/N: 093075-00Rev000 J/N: 190190 Cust.: Fujirebio Size: 1.875 X 0.8125 Die#: 0985D-L-64 CR: .0625 Die Line Does Not Print		<table border="1"> <tr> <td>Black</td> <td>300</td> <td>340</td> <td>Dieline</td> <td>Overall Varnish</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> </table>		Black	300	340	Dieline	Overall Varnish											<table border="1"> <tr> <td>K</td> <td>C</td> <td>M</td> <td>Y</td> </tr> <tr> <td colspan="4">Indichrome Plus (+)</td> </tr> <tr> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>O</td> <td>G</td> <td>V</td> <td>W</td> </tr> </table>		K	C	M	Y	Indichrome Plus (+)								O	G	V	W	Approved By Customer: _____ Date: _____ Note: We must have a signed proof before we can begin production.	
Black	300	340	Dieline	Overall Varnish																																		
K	C	M	Y																																			
Indichrome Plus (+)																																						
O	G	V	W																																			
Note: This proof is to show size, copy and color breaks. <input type="checkbox"/> This proof is color correct. Color: Actual colors will be matched on press to: PMS Book, On_Demand Solutions Four Color Book, On_Demand Solutions Indichrome Plus Color Book and/or approved Color Standards <input type="checkbox"/> This proof contains braille.		<input type="checkbox"/> OK to print <input type="checkbox"/> See Attached		<input type="checkbox"/> Another proof required																																		
<p style="text-align: center;">complete packaging individual solutionsSM Nosco makes it easier...</p> 																																						
651 S ML King Jr Ave • Waukegan, IL 60085 Phone (847) 336-4200 • FAX (847) 360-4924				 <p>For more information visit http://www2.nosco.com/problemsolved/</p>																																		

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION MEDICAL DEVICE USER FEE COVER SHEET		PAYMENT IDENTIFICATION NUMBER: (b)(4) Write the Payment Identification number on your check.	
A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/cover sheet.html			
1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code) FUJIREBIO DIAGNOSTICS INC 201 GREAT VALLEY PARKWAY MALVERN PA 19355 US 1.1 EMPLOYER IDENTIFICATION NUMBER (EIN) *****3954		2. CONTACT NAME Stacey Dolan 2.1 E-MAIL ADDRESS dolans@fdi.com 2.2 TELEPHONE NUMBER (include Area code) 610-240-3843 2.3 FACSIMILE (FAX) NUMBER (Include Area code)	
3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma) <u>Select an application type:</u> <input checked="" type="checkbox"/> Premarket notification(510(k)); except for third party <input type="checkbox"/> 513(g) Request for Information <input type="checkbox"/> Biologics License Application (BLA) <input type="checkbox"/> Premarket Approval Application (PMA) <input type="checkbox"/> Modular PMA <input type="checkbox"/> Product Development Protocol (PDP) <input type="checkbox"/> Premarket Report (PMR) <input type="checkbox"/> Annual Fee for Periodic Reporting (APR) <input type="checkbox"/> 30-Day Notice			
3.1 Select a center <input checked="" type="checkbox"/> CDRH <input type="checkbox"/> CBER 3.2 Select one of the types below <input checked="" type="checkbox"/> Original Application <u>Supplement Types:</u> <input type="checkbox"/> Efficacy (BLA) <input type="checkbox"/> Panel Track (PMA, PMR, PDP) <input type="checkbox"/> Real-Time (PMA, PMR, PDP) <input type="checkbox"/> 180-day (PMA, PMR, PDP)			
4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status) <input type="checkbox"/> YES, I meet the small business criteria and have submitted the required qualifying documents to FDA <input checked="" type="checkbox"/> NO, I am not a small business 4.1 If Yes, please enter your Small Business Decision Number:			
5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA? <input checked="" type="checkbox"/> YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.) <input type="checkbox"/> NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)			
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION. <input type="checkbox"/> This application is the first PMA submitted by a qualified small business, including any affiliates <input type="checkbox"/> This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only <input type="checkbox"/> The sole purpose of the application is to support conditions of use for a pediatric population <input type="checkbox"/> The application is submitted by a state or federal government entity for a device that is not to be distributed commercially			
7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).) <input type="checkbox"/> YES <input checked="" type="checkbox"/> NO			
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below. Department of Health and Human Services, Food and Drug Administration, Office of Chief Information Officer, 1350 Piccard Drive, 4th Floor Rockville, MD 20850 [Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]			
8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION (b)(4)		29-Dec-2010	

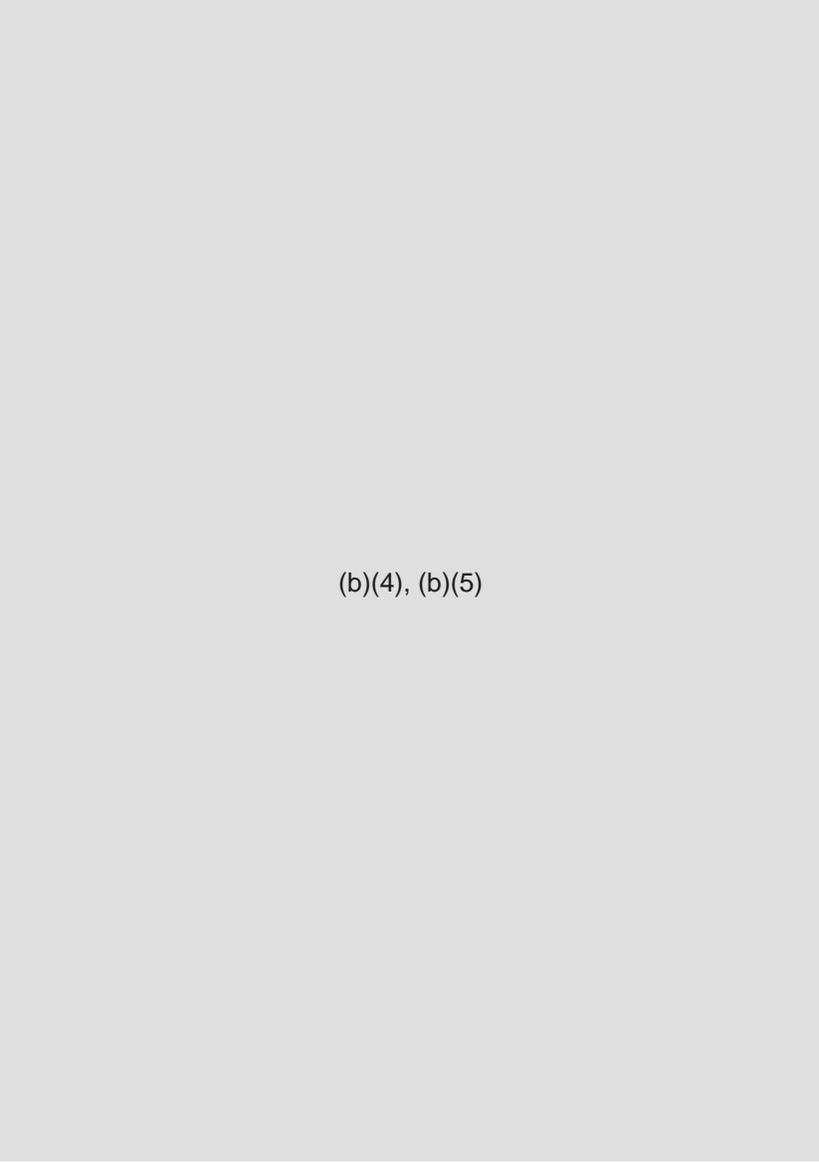
DRAFT



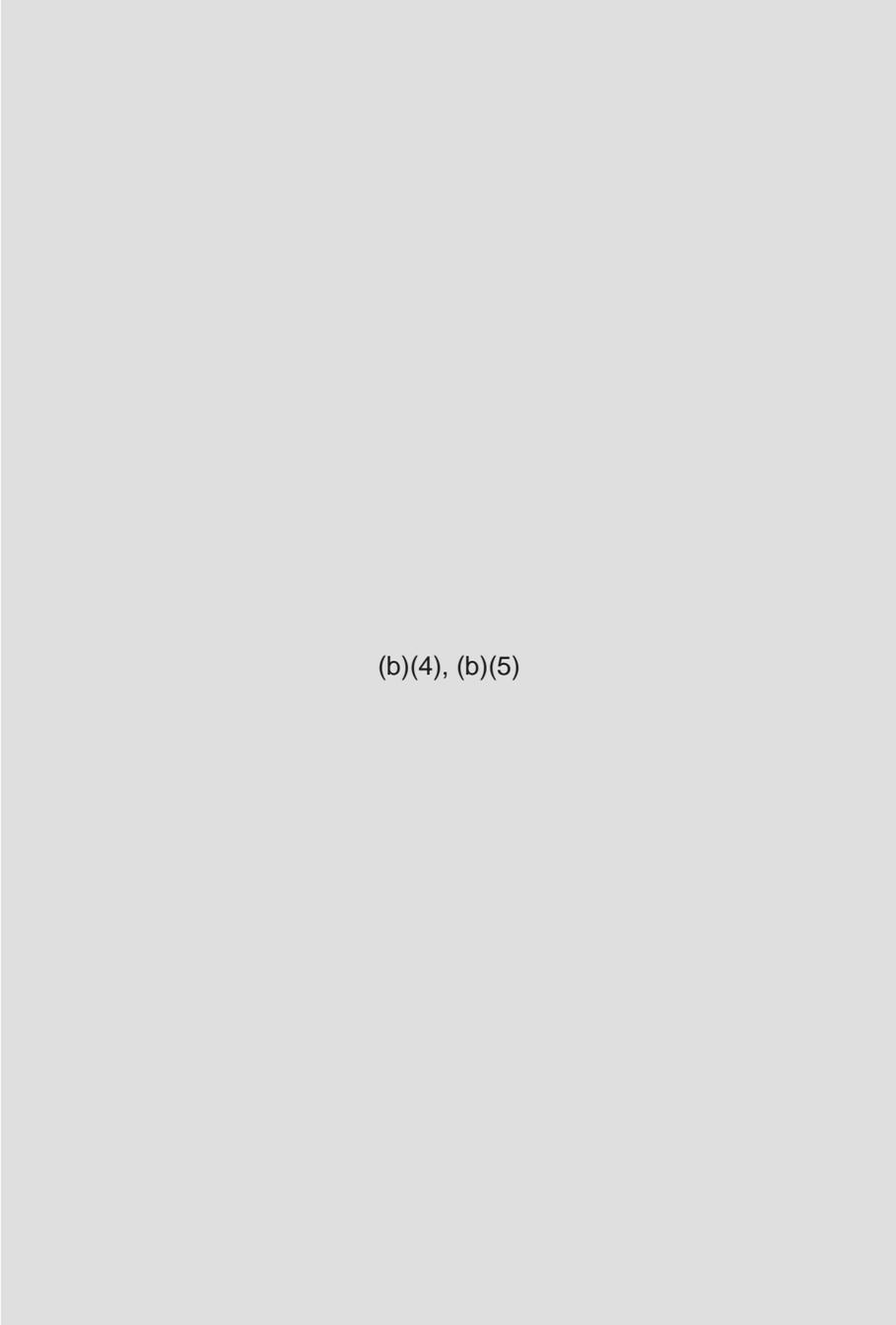
(b)(4), (b)(5)



(b)(4), (b)(5)



(b)(4), (b)(5)



(b)(4), (b)(5)

Department of Health and Human Services
Food and Drug Administration
STANDARDS DATA REPORT FOR 510(k)s
(To be filled in by applicant)

This report and the Summary Report Table are to be completed by the applicant when submitting a 510(k) that references a national or international standard. A separate report is required for each standard referenced in the 510(k).

TYPE OF 510(K) SUBMISSION

Traditional Special Abbreviated

STANDARD TITLE¹

Stability Testing of in vitro diagnostic reagents

Please answer the following questions

Yes No

Is this standard recognized by FDA²?

FDA Recognition number³ # 7-84

Was a third party laboratory responsible for testing conformity of the device to this standard identified in the 510(k)?

Is a summary report⁴ describing the extent of conformance of the standard used included in the 510(k)?
If no, complete a summary report table.

Does the test data for this device demonstrate conformity to the requirements of this standard as it pertains to this device?

Does this standard include acceptance criteria?
If no, include the results of testing in the 510(k).

Does this standard include more than one option or selection of tests?
If yes, report options selected in the summary report table.

Were there any deviations or adaptations made in the use of the standard?
If yes, were deviations in accordance with the FDA supplemental information sheet (SIS)⁵?

Were deviations or adaptations made beyond what is specified in the FDA SIS?
If yes, report these deviations or adaptations in the summary report table.

Were there any exclusions from the standard?
If yes, report these exclusions in the summary report table.

Is there an FDA guidance⁶ that is associated with this standard?
If yes, was the guidance document followed in preparation of this 510k?

Title of guidance: _____

¹ The formatting convention for the title is: [SDO] [numeric identifier] [title of standard] [date of publication]

² Authority [21 U.S.C. 360d], www.fda.gov/cdrh/stdsprog.html

³ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁴ The summary report should include: any adaptations used to adapt to the device under review (for example, alternative test methods); choices made when options or a selection of methods are described; deviations from the standard; requirements not applicable to the device; and the name and address of the test laboratory or

certification body involved in conformance assessment to this standard. The summary report includes information on all standards utilized during the development of the device.

⁵ The supplemental information sheet (SIS) is additional information which is necessary before FDA recognizes the standard. Found at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfStandards/search.cfm>

⁶ The online search for CDRH Guidance Documents can be found at www.fda.gov/cdrh/guidance.html

(b)(4)



Food and Drug Administration
Office of Device Evaluation &
Office of In Vitro Diagnostics

COVER SHEET MEMORANDUM

From: Reviewer Name JZL
Subject: 510(k) Number K110641
To: The Record

Please list CTS decision code _____

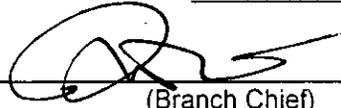
- Refused to accept (Note: this is considered the first review cycle, See Screening Checklist http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_5631/Screening%20Checklist%207%202%2007.doc)
- Hold (Additional Information or Telephone Hold).
- Final Decision (SE, SE with Limitations, NSE, Withdrawn, etc.).

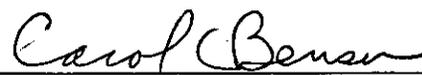
Please complete the following for a final clearance decision (i.e., SE, SE with Limitations, etc.):		YES	NO
Indications for Use Page	Attach IFU	✓	
510(k) Summary /510(k) Statement	Attach Summary	✓	
Truthful and Accurate Statement.	Must be present for a Final Decision	✓	
Is the device Class III?			✓
If yes, does firm include Class III Summary?	Must be present for a Final Decision		✓
Does firm reference standards? (If yes, please attach form from http://www.fda.gov/opacom/morechoices/fdaforms/FDA-3654.pdf)		✓	⊗
Is this a combination product? (Please specify category _____, see http://eroom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_413b/COMBINATION%20PRODUCT%20ALGORITHM%20(REVISED%203-12-03).DOC)			✓
Is this a reprocessed single use device? (Guidance for Industry and FDA Staff – MDUFMA - Validation Data in 510(k)s for Reprocessed Single-Use Medical Devices, http://www.fda.gov/cdrh/ode/guidance/1216.html)			✓
Is this device intended for pediatric use only?			✓
Is this a prescription device? (If both prescription & OTC, check both boxes.)		✓	
Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank?		✓	
Is clinical data necessary to support the review of this 510(k)? Did the application include a completed FORM FDA 3674, Certification with Requirements of ClinicalTrials.gov Data Bank? (If not, then applicant must be contacted to obtain completed form.)		✓	9a
Does this device include an Animal Tissue Source?			✓
All Pediatric Patients age ≤ 21			✓
Neonate/Newborn (Birth to 28 days)			✓
Infant (29 days - < 2 years old)			✓
Child (2 years - < 12 years old)			✓
Adolescent (12 years - < 18 years old)			✓
Transitional Adolescent A (18 - < 21 years old) Special considerations are being given to this group, different from adults age ≥ 21 (different device design or testing, different protocol procedures, etc.)			✓

Transitional Adolescent B (18 <= 21; No special considerations compared to adults => 21 years old)		✓ ✓ ✓
Nanotechnology		
Is this device subject to the Tracking Regulation? (Medical Device Tracking Guidance, http://www.fda.gov/cdrh/comp/guidance/169.html)	Contact OC.	

Regulation Number	Class*	Product Code
862.1660	I	JJX
(*If unclassified, see 510(k) Staff)		

Additional Product Codes: _____

Review: 	DC-11	5/25/11
(Branch Chief)	(Branch Code)	(Date)

Final Review: 	May 27, 2011
(Division Director)	(Date)

Li, Jinong

From: Gormley, John [JGormley@fdi.com]
Sent: Friday, May 27, 2011 10:49 AM
To: Li, Jinong
Cc: Dolan, Stacey
Subject: K110641 Primary Contact Change

Ms. Li,

Please accept this email as authorization to accept Stacey Dolan as the primary contact person for 510(k) K110641.

Thank you,
John C. Gormley
General Manager
Fujirebio Diagnostics, Inc. (FDI)



940 Crossroads Blvd.

Seguin, TX 78130

Phone: 1-800-531-7963 ext 210

Fax: 1-830-372-4130

THIS E-MAIL MAY CONTAIN CONFIDENTIAL OR PROPRIETARY MATERIAL FOR THE SOLE USE OF THE INTENDED RECIPIENT. ANY REVIEW, USE, DISTRIBUTION OR DISCLOSURE BY OTHERS IS STRICTLY PROHIBITED. IF YOU ARE NOT THE INTENDED RECIPIENT, OR AUTHORIZED TO RECEIVE THE INFORMATION FROM THE RECIPIENT, PLEASE CONTACT THE SENDER BY REPLY E-MAIL AND DELETE ALL COPIES OF THIS MESSAGE.

**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY ONLY TEMPLATE**

A. 510(k) Number:

k110641

B. Purpose for Submission:

New device

C. Measurand:

Quality control materials for Vitamin D assays

D. Type of Test:

Quality Control Materials

E. Applicant:

Fujirebio Diagnostics, Inc.

F. Proprietary and Established Names:

Fujirebio Diagnostics Vitamin D Control

G. Regulatory Information:

Product Code	Classification	Regulation Section	Panel
JJX	Class I, reserved	21 CFR 862.1660 Quality Control Material	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

Refer to indication for use below.

2. Indication(s) 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.

3. Special conditions for use statement(s):

For *in vitro* diagnostic use only.

Fujirebio Diagnostics Vitamin D Control is made from human source material, and therefore should be treated as potentially infectious. Each human donor unit used to manufacture this control was tested by FDA accepted methods and found non-reactive for Hepatitis B Surface Antigen (HBsAg), antibody to Hepatitis C (HCV), antibody to HIB-1/HIV-2, and antibody to Treponema Pallidum (Syphilis). This product may also contain other human pathogens for which there are no approved tests. All human source material should be considered potentially infectious and handled with the same precautions used with patient specimens.

4. Special instrument requirements:

None

I. Device Description:

The Fujirebio Diagnostics Vitamin D Control is prepared from human serum, protein (bovine), purified biochemical materials, and chemicals. It also contains Proclin 300® and Gentamicin as preservatives.

The controls are provided in lyophilized form. The control levels contain Vitamin D at the corresponding target concentrations.

Analyte	Analyte Form	Target Concentrations (ng/mL)		
		Level 1	Level 2	Level 3
25 (OH) Vitamin D	25 (OH) D2	0	10	10
	25 (OH) D3	10	20	60

J. Substantial Equivalence Information:

1. Predicate device name(s):

Bio-Rad Liquichek™ Specialty Immunoassay Control – 25-OH Vitamin D

2. Predicate 510(k) number(s):

k043108

3. Comparison with predicate:

Items	Fujirebio Diagnostics Vitamin D Control (Candidate Device)	Bio-Rad Liquichek™ Specialty Immunoassay Control – 25-OH Vitamin D (Predicate Device)

Similarity		
Intended Use	Same	For use as an assayed quality control serum to monitor the precision of laboratory testing procedures for the measurement of 25-OH Vitamin D
Analyte(s)	Same	25-OH Vitamin D
Levels of Controls	Same	3
Matrix	Same	Human Serum with additives
Differences		
Vitamin D Analyte Forms	25(OH) Vitamin D2 25(OH) Vitamin D3	25(OH) Vitamin D3
Other Analytes	None	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

K. Standard/Guidance Document Referenced (if applicable):

EN standard, 13640 – Stability testing of *In Vitro* diagnostic reagents.

L. Test Principle:

Not applicable

M. Performance Characteristics (if/when applicable):1. Analytical performance:a. *Precision/Reproducibility:*

Not applicable

b. *Linearity/assay reportable range:*

Not applicable

c. *Traceability, Stability, Expected values (controls, calibrators, or methods):*Traceability

The Vitamin D2 and D3 antigen material were obtained from commercial vendors. The

Vitamin D2 and D3 antigen material are supplied as a white solid. The Vitamin D2 and Vitamin D3 antigens are solubilized in 95% Ethyl Alcohol and subsequently spiked into the 25-hydroxy Vitamin D2/D3 Control Matrix to manufacture the Vitamin D Level 1, 2, and 3 controls.

Value Assignment:

- The control ranges as determined using DiaSorin LIAISON, DiaSorin RIA, IDS EIA and LC-MS/MS assays are provided in the assigned value sheet for each lot release. Each control range was determined from a minimum of 20 measurements per assay using 2 reagent/calibrator lots, 2 instruments, in 2 runs with 5 replicates each run. The ranges were determined as mean +/- 2 SD for DiaSorin LIAISON, DiaSorin RIA assays or mean +/-30% for IDS EIA and LC-MS/MS assays.
- In the labeling the sponsor recommends that each end user laboratory establish its own means and acceptable ranges and use the assigned value sheet as guidance only.

Stability:

- Shelf life stability:
Real-time testing at 2-8°C were conducted and is still on-going. The stability study protocol and acceptance criteria have been reviewed and found to be acceptable. The current test results support a shelf life of 12 months at 2-8°C.
- Reconstituted Stability:
The stability study protocol and acceptance criteria to determine the reconstituted stability and freeze/thaw cycle of the controls have been reviewed and found to be acceptable. The control solutions are stable for 14 days when stored tightly capped at 2-8°C, and stable for 63 days when stored at -10°C. Controls may be frozen and thawed repeatedly for up to 9 cycles

d. Detection limit:

Not applicable

e. Analytical specificity:

Not applicable

f. Assay cut-off:

Not applicable

2. Comparison studies:

a. Method comparison with predicate device:

Not applicable

b. Matrix comparison:

Not applicable

3. Clinical studies:

a. Clinical Sensitivity:

Not applicable

b. Clinical specificity:

Not applicable

c. Other clinical supportive data (when a. and b. are not applicable):

Not applicable

4. Clinical cut-off:

Not applicable

5. Expected values/Reference range:

The control ranges as determined using DiaSorin LIAISON, DiaSorin RIA, IDS EIA and LC-MS/MS assays are provided in the assigned value sheet for each lot release.

N. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

O. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.

P. Other Supportive Device and Instrument Information:

There are no post-market signals related to this device.

Stability testing was performed with the DiaSorin Vitamin D RIA assay.

On 5/5/2011, I emailed the sponsor and told them that it is their responsibility to verify the device stability on all the assays. On 5/16/2011, the sponsor sent email response with the following statement: "FDI will continue to monitor stability using the Diasorin RIA and will verify stability on all other assay platforms which are referenced in the package insert."

Q. Administrative Information:

1. Applicant contact information:

a. *Name of applicant:*

Fujirebio Diagnostics, Inc.

b. *Mailing address:*

201 Great Valley Parkway

Malvern, PA, 19355, US

c. *Phone #:*

(610) 240-3843

d. *Fax #:*

(610) 240-3803

e. *E-mail address (optional):*

dolans@fdi.com

f. *Contact:*

Stacey Dolan

2. Review documentation:

3/8/11, I was assigned to this submission.

(b)(4)

3. Substantial Equivalence Discussion:

	Yes	No
1. Same Indication Statement?		If YES = Go To 3
2. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?		If YES = Stop NSE
3. Same Technological Characteristics?		If YES = Go To 5
4. Could The New Characteristics Affect Safety Or Effectiveness?		If YES = Go To 6
5. Descriptive Characteristics Precise Enough?	(b)(4), (b)(5)	If NO = Go To 8 If YES = Stop SE
6. New Types Of Safety Or Effectiveness Questions?		If YES = Stop NSE
7. Accepted Scientific Methods Exist?		If NO = Stop NSE
8. Performance Data Available?		If NO = Request Data
9. Data Demonstrate Equivalence?		Final Decision: SE

Note: See

http://croom.fda.gov/eRoomReq/Files/CDRH3/CDRHPremarketNotification510kProgram/0_4148/FLOWCHART%20DECISION%20TREE%20.DOC for Flowchart to assist in decision-making process. Please complete the following table and answer the corresponding questions. "Yes" responses to questions 2, 4, 6, and 9, and every "no" response requires an explanation.

- a. Explain how the new indication differs from the predicate device's indication:
- b. Explain why there is or is not a new effect or safety or effectiveness issue:
- c. Describe the new technological characteristics:
- d. Explain how new characteristics could or could not affect safety or effectiveness:
- e. Explain how descriptive characteristics are not precise enough:

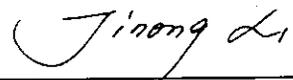
(b)(4)

(b)(4)

- f. *Explain new types of safety or effectiveness question(s) raised or why the question(s) are not new:*
- g. *Explain why existing scientific methods can not be used:*
- h. *Explain what performance data is needed:*
- i. *Explain how the performance data demonstrates that the device is or is not substantially equivalent:*

The submitted information in this premarket notification is complete and supports a substantial equivalence decision. See the decision summary template in section M.2.a. above for more information.

R. Reviewer Name and Signature:



Jinong Li
CDRH/OIVD/DCTD

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.

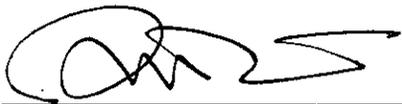
Prescription Use X
(Part 21 CFR 801 Subpart D)

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)



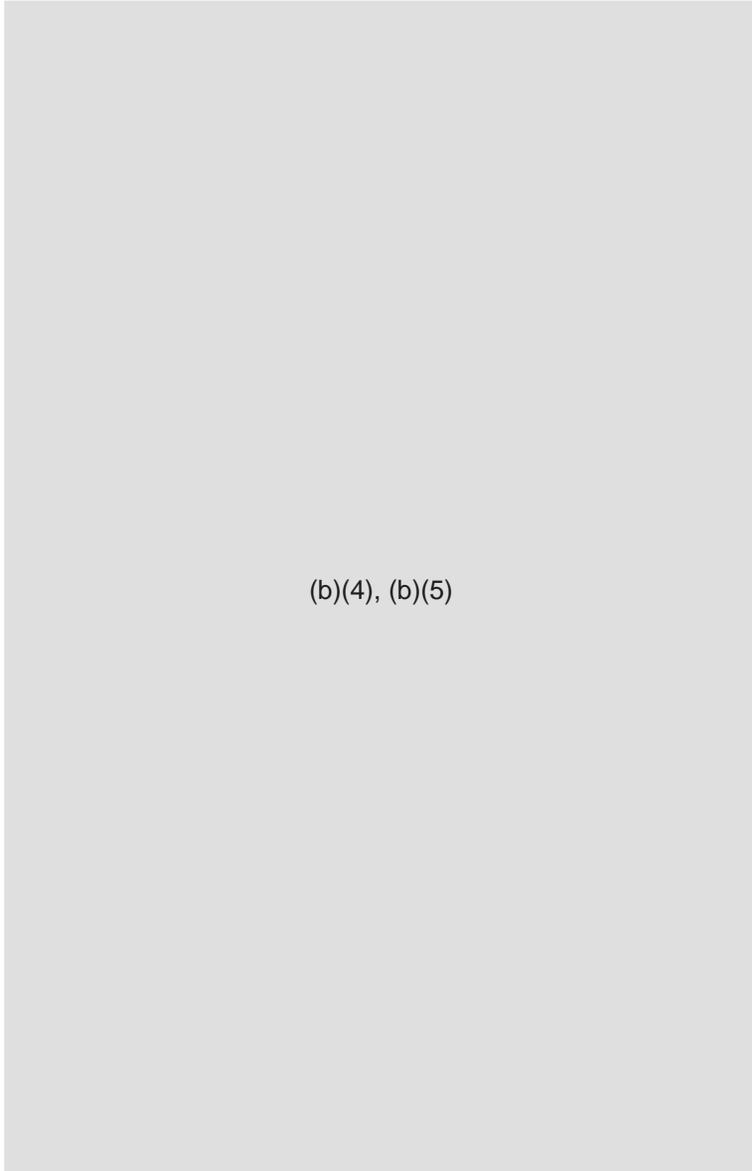
Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K110641

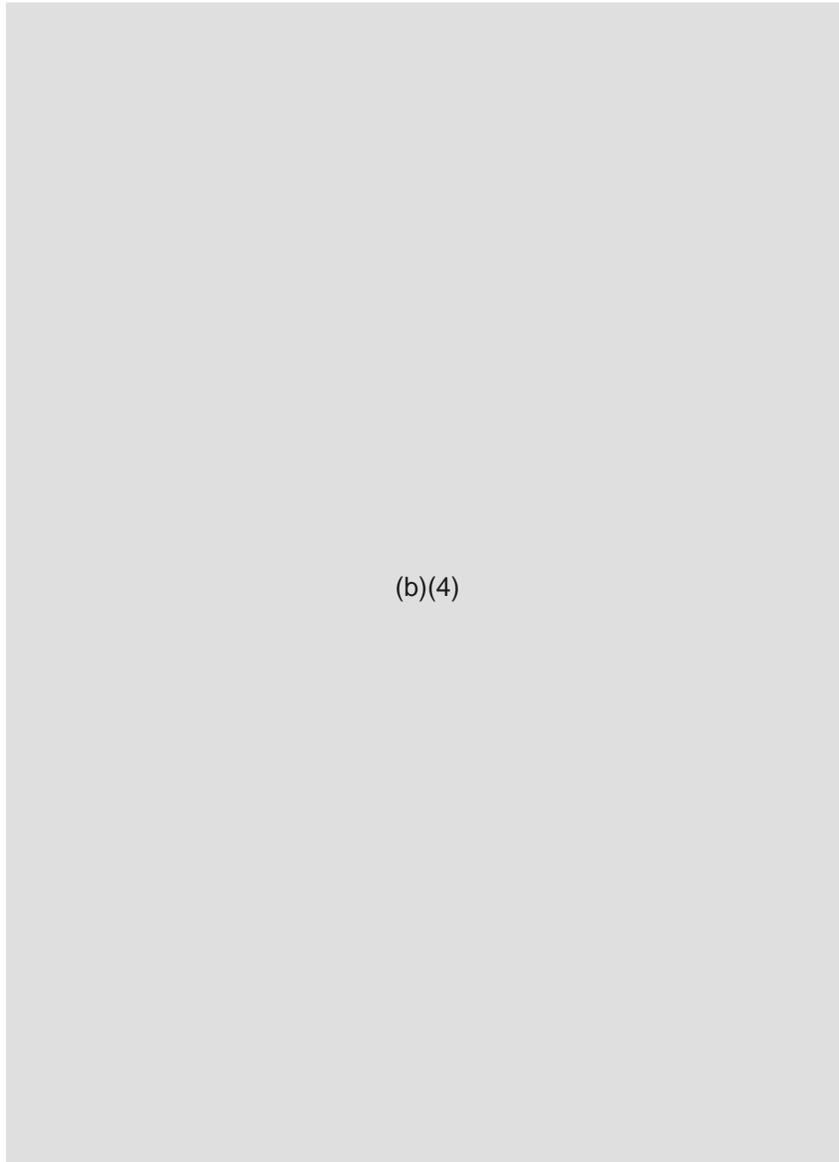
Page 1 of 1

Revised Label

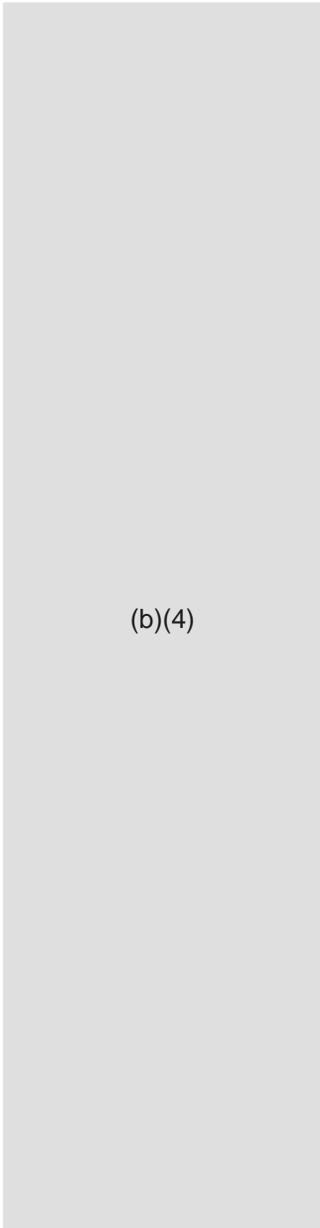
DRAFT



(b)(4), (b)(5)

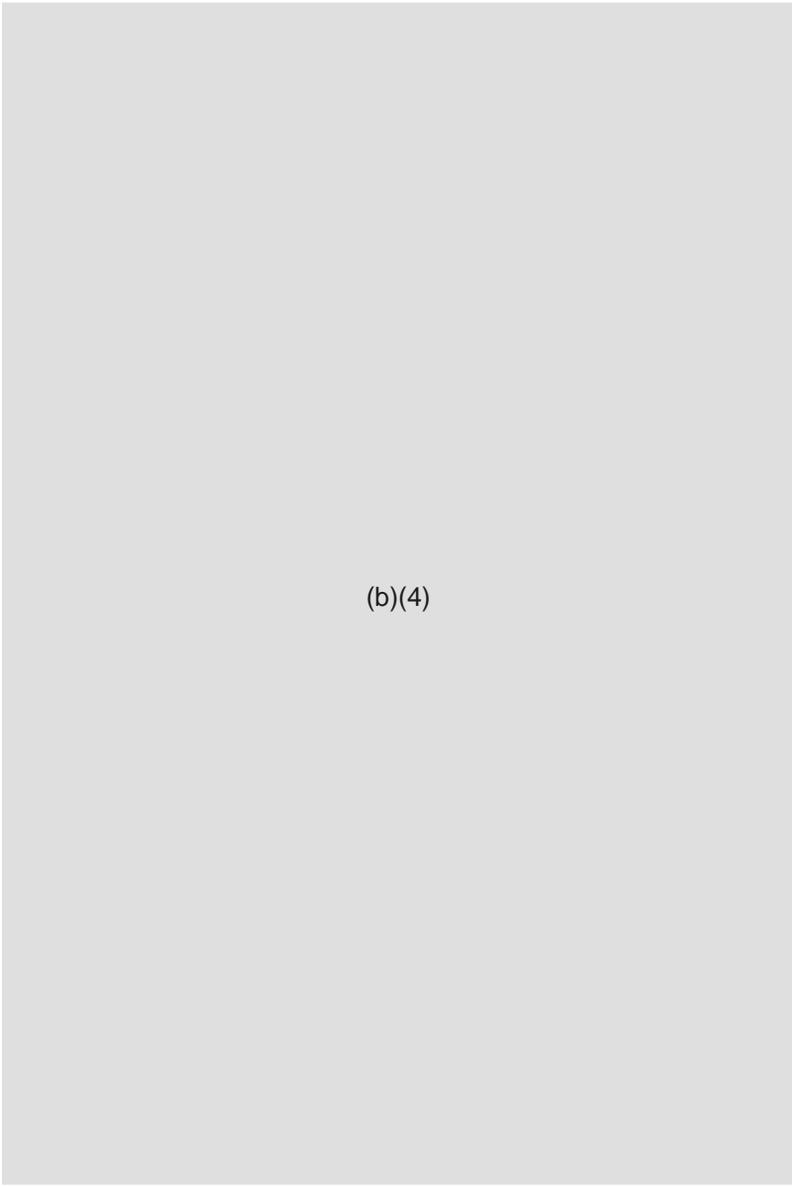


(b)(4)

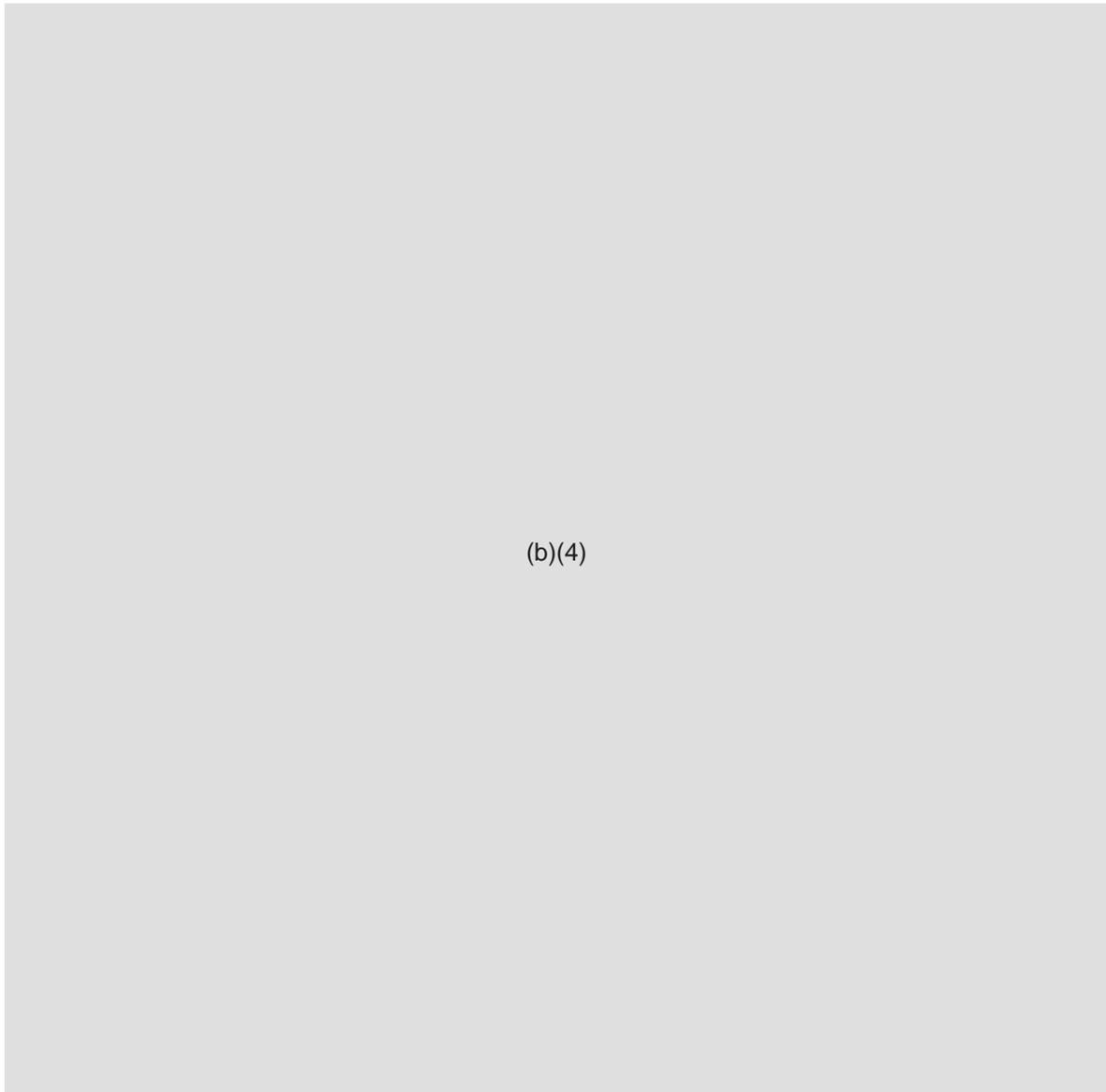


(b)(4)

3



(b)(4)



(b)(4)

Li, Jinong

From: Dolan, Stacey [DolanS@FDi.com]
Sent: Monday, May 16, 2011 4:58 PM
To: Li, Jinong
Subject: RE: K110641 Fujirebio vitamin D control

Jinong,

Here is the statement you requested:

(b)(4), (b)(5)

If you need further information regarding this, please let me know.

Thanks,
Stacey

From: Li, Jinong [mailto:Jinong.Li@fda.hhs.gov]
Sent: Monday, May 09, 2011 4:27 PM
To: Dolan, Stacey
Subject: RE: K110641 Fujirebio vitamin D control

(b)(4), (b)(5)

Thanks,
Jinong

From: Dolan, Stacey [mailto:DolanS@FDi.com]
Sent: Thursday, May 05, 2011 9:42 PM
To: Li, Jinong
Cc: Dickson, Diana
Subject: RE: K110641 Fujirebio vitamin D control

Hi Dr. Li,

(b)(4), (b)(5)

Do you think we should have a teleconference to discuss this? If so, I will be out of the office tomorrow and Monday but any other day next week would work.

Thanks again for all your help with this submission!

Thanks,
Stacey

(b)(4), (b)(5)

From: Li, Jinong [mailto:Jinong.Li@fda.hhs.gov]
Sent: Thursday, May 05, 2011 4:15 PM
To: Dolan, Stacey
Subject: RE: K110641 Fujirebio vitamin D control

Hi Stacey,

(b)(4), (b)(5)

Thanks,
Jinong

From: Dolan, Stacey [mailto:DolanS@FDi.com]
Sent: Thursday, May 05, 2011 3:31 PM
To: Li, Jinong

Subject: RE: K110641 Fujirebio vitamin D control

Hi Dr. Li,

(b)(4), (b)(5)

Thanks,
Stacey

From: Li, Jinong [mailto:Jinong.Li@fda.hhs.gov]
Sent: Thursday, May 05, 2011 11:31 AM
To: Dolan, Stacey
Subject: RE: K110641 Fujirebio vitamin D control

Hi Stacey,

(b)(4), (b)(5)

Please send response to these questions.

Thanks,
Jinong

From: Dolan, Stacey [mailto:DolanS@FDi.com]
Sent: Tuesday, May 03, 2011 8:49 AM
To: Li, Jinong
Subject: RE: K110641 Fujirebio vitamin D control

Good morning Dr. Li,

(b)(4), (b)(5)

If you have any more questions or need further information just let me know.

Thanks!
Stacey

From: Li, Jinong [mailto:Jinong.Li@fda.hhs.gov]
Sent: Friday, April 29, 2011 11:23 AM
To: Dolan, Stacey
Subject: RE: K110641 Fujirebio vitamin D control

Hi Stacey,
Thank you for your email response.

(b)(4), (b)(5)

Thanks,

Jinong

From: Dolan, Stacey [mailto:DolanS@FDi.com]
Sent: Friday, April 15, 2011 12:48 PM
To: Li, Jinong
Subject: RE: K110641 Fujirebio vitamin D control

Dr. Li,

I appreciate your call regarding the Vitamin D Control submission. Here are the answers to your questions below:

(b)(4), (b)(5)

(b)(4), (b)(5)

Attached please find the updated 510k summary.

Thanks for all your help with this submission.

Stacey

Stacey Dolan
Regulatory Affairs Specialist
Fujirebio Diagnostics Inc.
201 Great Valley Pkwy
Malvern, PA 19355
610.240.3843
Fax: 610.240.3803
dolans@fdi.com

From: Li, Jinong [mailto:Jinong.Li@fda.hhs.gov]
Sent: Thursday, April 14, 2011 12:49 PM
To: Dolan, Stacey
Subject: K110641 Fujirebio vitamin D control

Hi Stacy,

It was nice talking to you earlier this morning.

Here's the few items that we talked about regarding your vitamin D control submission k 110641:

(b)(4), (b)(5)

(b)(4), (b)(5)

Thanks,

*Jinong Li, Ph.D., DABCC
Scientific Reviewer
FDA/CDRH/OIVD/DCTD
Food and Drug Administration
10903 New Hampshire Ave.
WO66, G454
Silver Spring, MD 20993-0002
301-796-4142-phone
301-847-8513-fax
Jinong.li@fda.hhs.gov*

THIS MESSAGE IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If you have received this document in error, please immediately notify us by email or telephone.

**510(k) "SUBSTANTIAL EQUIVALENCE"
DECISION-MAKING PROCESS**

(b)(4), (b)(5)

- * 510(k) Submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.
- ** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.
- *** Data maybe in the 510(k), other 510(k)s, the Center's classification files, or the literature.