Attachment 5

DEC 2 0 2010

510(k) Summary of Safety and Effectiveness
PT-Multi Calibrator

(a) The device name, including both the trade or proprietary name and the common or usual name and the classification name of the device.

Trade or proprietary name:	PT-Multi Calibrator
Common or usual name:	Calibrators
Classification name:	Multipurpose System for In Vitro Coagulation Studies (21CFR 864.5425)

(b) The establishment registration number, if applicable, of the owner or operator submitting the premarket notification submission.

Establishment Registration Numbers:	Site Activity
9610806	Manufacturer: Siemens Healthcare Diagnostics Marburg GmbH Emil-von-Behring Str. 76 35041 Marburg, Germany
2517506	Distributor/Applicant: Siemens Healthcare Diagnostics Inc. Glasgow Site Bldg. 500, M.S. 514 P.O. Box 6101 Newark, Delaware 19714-6101

(c) The class in which the device has been put under Section 513 of the Act and, if known, its appropriate panel; or, if the owner or operator determines that the device has not been classified under such section, a statement of the determination and the basis for the person's determination that the device is not so classified.

Class: II
Panel: Hematology
Product Code: GGN

(d) Action taken by the person required to register to comply with the requirements of the Act under Section 514 for performance standards.

To date, no performance standards have been finalized for this device.

(e) Device Description

PT-Multi Calibrator is a set of certified plasmas for local PT/INR calibration and/or local verification of the INR system for plasma based procedures using Siemens Dade® Innovin® or Thromborel® S reagents on Siemens BCS® Coagulation Systems.

The calibrator levels are manufactured using a combination of normal and depleted human plasma.

(f) Device Intended Use

PT-Multi Calibrator is intended as a calibrator set for local PT/INR calibration and/or local verification of the INR system for plasma based procedures with designated Siemens thromboplastins Dade® Innovin® or Thromborel® S on the BCS® / BCS® XP Systems.

(g) A statement indicating the device is similar to and/or different from other products of comparable type in commercial distribution, accompanied by data to support the statement. This information may include an identification of similar products, materials, design considerations, energy expected to be used or delivered by the device, and a description of the operational principles of the device.

The PT-Multi Calibrator is substantially equivalent in intended use to HemosIL INR Validate®, HemosIL®-ISI Calibrate, ISI web Software (K090563), Instrumentation Laboratories Co., Lexington, MA 02421. Both devices are intended as calibrators for monitoring the accuracy and control of oral anticoagulant therapy.

(e) Suitability of this Device is supported by the data provided below

Method Comparison studies were conducted at three different sites using at least two lots of PT-Multi Calibrator and the conventional local ISI/MNPT. Precision was evaluated at three different sites with at least two lots of PT-Multi Calibrator. Results of the studies are summarized in the tables below.

	BCS System							
					without extrapolation		with extrapolation (factor 1.2)	
	Local Test System ISI / MNPT	MNPT	ISI	PT Multi Calibrator (lot #) Local INR Calibration	n	Regression Analysis	n	Regression Analysis
Denver	Thromborel S	10,9	1,12	37591	138	y=0.95x -0.00	139	y=0.95x -0.00
	lot 545197			37592	136	y=0.92x +0.06	139	y=0.92x+0.06
	Innovin	8,4	0,92	37591	136	y=0.97x -0.10	N/A	N/A
	lot 536999			37592	130	y=0.97x -0.03	N/A	N/A
Munich	Thromborel S	11,5	1,12	37591	118	y= 0.97x -0.02	123	y= 0.97x -0.02
	lot 545116			37592	118	y= 0.93x +0.06	123	y= 0.93x +0.05
	Innovin	8,7	0,92	37591	106	y= 1.10x -0.20	N/A	N/A
	lot 536997			37592	102	y= 1.09x -0.13	N/A	N/A
Marburg	Thromborel S	12,2	1,05	37591	118	y=0.92x +0.05	122	y=0.92x +0.05
	lot 545248			38585	110	y=1.02x + 0.01	121	y=1.03x + 0.00
	Innovin	8,4	0,93	37591	112	y=0.94x -0.02	N/A	N/A
	lot 539126			38585	107	y=0.98x -0.02	N/A	N/A
all sites	Thromborel S			37591, 37592,38585	738	y=0.93x+0.03	768	y=0.94x+0.03
	Innovin			37591, 37592,38585	693	y=0.97x-0.04	N/A	N/A

20 Day ANOVA Precision Studies on the BCS System

Denver	Local Test System								PT-Multi Calibrator lot 537591								PT-Multi Calibrator lot 537592							
	Innovin lot 536999				Thromborel S lot 545197				Innovin lot 536999				Thromborel S lot 545197				Innovin lot 536999				Thromborel S lot 545197			
	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP
Mean (INR)	2.15	3.0	1.01	4.01	2.4	3.7	1.01	3.6	2.0	2.9	[illegible]	3.8	2.4	3.6	1.01	3.6	2.14	2.9	[illegible]	3.8	2.3	3.6	1.01	3.5
Repeatability %	1.7	1.1	1.2	0.8	3.7	1.3	1.2	0.9	1.8	1.2	[illegible]	0.8	3.7	1.3	1.2	0.9	1.8	1.1	[illegible]	0.8	3.6	1.3	1.0	0.9
Within-day-CV %	1.7	1.5	1.2	1.5	3.7	1.6	1.7	1.5	1.8	1.5	[illegible]	1.5	3.7	1.6	1.6	1.5	1.8	1.5	[illegible]	1.5	3.6	1.5	1.5	1.5
Between-run-CV %	0.0	0.9	0.0	1.3	0.5	0.9	1.2	1.1	0.0	0.9	[illegible]	1.3	0.5	0.9	1.0	1.2	0.0	0.9	[illegible]	1.3	0.5	0.9	1.1	1.1
Between-day CV %	0.5	0.7	0.0	0.7	1.5	0.3	0.6	0.0	0.5	0.7	[illegible]	0.7	1.5	0.3	0.6	0.0	0.5	0.7	[illegible]	0.7	1.4	0.4	0.4	0.5
Within-device-CV %	1.8	1.6	1.2	1.6	4.0	1.6	1.8	1.5	1.9	1.7	[illegible]	1.7	4.0	1.6	1.7	1.5	1.8	1.6	[illegible]	1.6	3.9	1.6	1.6	1.5

Munich	Local Test System								PT-Multi Calibrator lot 537591								PT-Multi Calibrator lot 537592							
	Innovin lot 536967				Thromborel S lot 545116				Innovin lot 536967				Thromborel S lot 545116				Innovin lot 536967				Thromborel S lot 545116			
	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP
Mean (INR)	2.13	2.8	1.01	3.41	2.5	3.7	1.1	3.4	2.2	2.9	1.01	3.61	2.4	3.5	1.01	3.3	2.2	2.9	1.01	3.6	2.4	3.5	1.01	3.2
Repeatability %	1.2	0.5	0.5	0.5	3.7	0.6	0.9	0.6	1.3	0.6	0.5	0.5	3.7	0.6	1.1	0.6	1.3	0.6	0.5	0.5	3.6	0.6	1.0	0.6
Within-day-CV %	1.8	1.0	0.7	0.8	5.0	1.1	1.4	1.0	1.9	1.0	0.8	0.8	5.0	1.1	1.5	1.0	1.9	1.0	0.8	0.8	4.9	1.0	1.5	1.0
Between-run-CV %	1.3	0.5	0.6	0.6	3.3	1.0	1.1	1.0	1.4	0.5	0.6	0.6	3.3	1.1	1.1	1.0	1.4	0.4	0.6	0.6	3.3	1.0	1.1	1.0
Between-day CV %	0.0	0.8	1.1	1.9	0.0	0.0	1.5	2.3	0.0	0.9	1.2	1.9	0.0	0.0	1.5	2.3	0.0	0.9	1.2	1.9	0.0	0.0	1.3	2.3
Within-device-CV %	1.8	1.1	1.3	2.0	5.0	1.1	2.1	3.8	1.9	1.2	1.5	2.1	5.0	1.1	2.2	3.8	1.9	1.1	1.4	2.1	4.9	1.0	2.0	3.7

Marburg	Local Test System								PT-Multi Calibrator lot 537591								PT-Multi Calibrator lot 537592							
	Innovin lot 539126				Thromborel S lot 545248				Innovin lot 539126				Thromborel S lot 545248				Innovin lot 539126				Thromborel S lot 545248			
	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP	CPP	C2	NPP	PPP
Mean (INR)	2.2	3.0	1.01	3.8	2.7	3.8	1.0	3.3	2.1	2.8	1.01	3.6	2.5	3.5	1.01	3.1	2.2	3.0	1.01	3.7	2.7	3.9	1.01	3.3
Repeatability %	1.3	0.8	0.7	0.4	4.7	0.5	0.9	0.7	1.3	0.7	0.7	0.4	4.7	0.5	1.0	0.6	1.3	0.7	0.7	0.4	4.7	0.5	1.0	0.7
Within-day-CV %	1.4	0.9	0.7	0.9	4.8	1.4	1.0	1.3	1.4	0.9	0.7	0.9	4.8	1.4	1.0	1.3	1.4	1.0	0.7	0.9	4.8	1.4	1.0	1.3
Between-run-CV %	0.4	0.7	0.0	0.8	1.0	1.3	0.5	1.1	0.5	0.7	0.2	0.8	0.8	1.3	0.3	1.1	0.5	0.7	0.0	0.8	1.1	1.3	0.4	1.1
Between-day CV %	0.9	1.3	0.6	1.1	2.3	2.2	0.9	0.3	1.2	1.3	0.6	1.1	2.3	2.2	1.0	0.3	0.8	1.3	0.6	1.0	2.3	2.2	1.0	0.4
Within-device-CV %	1.6	1.6	0.9	1.4	5.4	2.7	1.4	1.3	1.8	1.6	0.9	1.4	5.3	2.6	1.4	1.3	1.6	1.6	0.9	1.4	5.4	2.7	1.4	1.3

Sample legend:

CPP	Control Plasma P
C2	Ci-Trol 2
NPP	normal plasma pool
PPP	pathological plasma pool

-* below lowest calibrator

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center – WO66-0609
Silver Spring, MD 20993-0002

Siemens Healthcare Diagnostics Inc.
c/o Mr. Radames Riesgo
Regulatory Affairs & Compliance Manager
Glasgow Business Community (GBC)
PO Box 6101 MS 514
Newark, DE 19702

DEC 2 0 2010

Re: k093848
Trade/Device Name: PT-Multi Calibrator
Regulation Number: 21 CFR §864.5425
Regulation Name: Multipurpose System for In Vitro Coagulation Studies
Regulatory Class: Class II
Product Code: GGN, JIS
Dated: November 29, 2010
Received: November 30, 2010

Dear Mr. Riesgo:

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

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

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed

predicate device results in a classification for your device and thus, permits your device to proceed to the market.

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

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

Sincerely yours,

Maria M Chan

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

Enclosure

Attachment 4

Indications for Use Statement

510(k) Number (if known): k093848

Device Name: PT-Multi Calibrator

DEC 2 0 2010

Indications for Use:

Intended Use: PT-Multi Calibrator is intended as a calibrator set for local PT/INR calibration and/or local verification of the INR system for plasma based procedures with designated Siemens thromboplastins Dade® Innovin® or Thromborel® S on the BCS® / BCS® XP Systems.

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

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

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

Division Sign-Off

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Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K093848