MAY - 1 2012

510(K) SUMMARY

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

The assigned 510(k) number is: k110212

A. Submitter:

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Date Prepared: April 12, 2012

B. Device Names:

Classification name	Prothrombin Time Test
Common/usual name	Prothrombin Time Test
Proprietary name	Alere INRatio®2 PT/INR Monitoring System (Professional Use) Alere INRatio®2 PT/INR Home Monitoring System Alere INRatio®2 PT/INR Test Strip

C. Predicate Devices:

INRatio® PT Monitoring System, K020679
INRatio® PT Monitoring System, K021923
INRatio® 2 PT/INR Monitoring System, K072727
INRatio® PT/INR Test Strip, K092987

D. Device Description:

The INRatio2 PT/INR Monitoring Systems (Professional and Home) perform a modified version of the one-stage Prothrombin Time test, using commercially available recombinant human thromboplastin (rhTP) reagent. The clot formed in the Prothrombin Time (PT) reaction is detected by a change in the electrical impedance of the sample during the coagulation process. The system consists of a monitor and disposable test strips. The monitor heats the test strip to the proper reaction temperature; a measure clot impedance and provides a result on a screen (user interface). The clotting reaction occurs on the Test Strip after the blood sample is applied. An International Normalized Ratio (INR) value is calculated from measured Prothrombin Time and the INR is displayed on the monitor to the user/patient.

E. Intended Uses:

Alere INRatio®2 PT/INR Monitoring System (Professional Use): The Alere INRatio®2 PT/INR Monitoring System (Professional Use), consisting of the INRatio®2 Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time by health care professionals. The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended to be used for screening purposes.

Limitations: The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

Alere INRatio®2 PT/INR Home Monitoring System: The Alere INRatio®2 PT/INR Home Monitoring System, consisting of the INRatio®2 Home Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin therapy on clotting time by properly selected suitably trained users (by prescription for home use or other order of a treating physician). Patients must be stabilized (>6 weeks) on warfarin therapy. The The Alere INRatio®2 PT/INR Home Monitoring System is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Home Monitoring System is not intended to be used for screening purposes.

Limitations: The Alere INRatio®2 PT/INR Home Monitoring System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

F. Comparison with the Predicate Devices:

The intended use (assay type and intended users) and the operation of the INRatio2 PT/INR Monitoring Systems (Professional and Home) and associated accessories and reagents have not changed. The INRatio2PT/INR Monitoring Systems (Professional or Home) are intended to measure International Normalized Ratio (INR) from fresh, capillary whole blood samples by both healthcare professional users and lay (trained patient users. The systems are not intended for screening. Based on the data and information presented here, the INRatio2 PT/INR Monitoring Systems (Professional or Home), when used with the User Guide by both Healthcare Professionals and Trained Patients, performed equivalently to the INRatio2 PT/INR Monitoring System K072727).

Furthermore, the INRatio2 PT/INR Test Strip is substantially equivalent to the previously cleared INRatio PT/INR Test Strip (K092987) currently marketed and distributed by Alere

North America. The current and modified INRatio2 PT/INR Test Strips both catalyze a clotting reaction in fresh, finger stick capillary whole blood samples The INRatio2 PT/INR Test Strips have a lower blood volume requirement. The INRatio2 PT/INR Test Strips can be used with the INRatio2 PT/INR monitors (Professional or Home).

The INRatio®2 PT/INR Monitoring Systems (Professional Use and Home-use) are not intended for use in the quantitative determination of the international normalized ratio (INR) to monitor the effect of oral anticoagulant (warfarin) therapy on clotting time on patients who are transitioning from heparin treatment to warfarin therapy.

Nonclinical Data:

Performance testing verified that the modified INRatio2 PT/INR Test Strips have equivalent or better performance compared to the previously cleared INRatio PT/INR Test Strips with respect to precision, accuracy, and potential interferents when used with the INRatio2 PT/INR Monitoring Systems (Professional or Home). The performance claims currently in the labeling have been changed to reflect the performance of the INRatio2 PT/INR Test Strips.

G. Clinical Data

Clinical testing validated that the INRatio2 PT/INR Monitoring Systems (Professional and Home) utilizing the INRatio2 PT/INR Test Strips, when used by trained patient users or healthcare professionals, performed with acceptable accuracy compared to the reference method (the Sysmex CA-560 Anticoagulation Analyzer). Both user populations generated INR values with the INRatio2 PT/INR Monitoring Systems (Professional or Home), utilizing the INRatio2 PT/INR Test Strip, that were deemed accurate relative to the reference method, per ISO 17593:2007.

H. Conclusions Drawn from Testing

Based on the data and information presented here, the INRatio2 PT/INR Monitoring Systems (Professional and Home) , when used with the INRatio2 PT/INR Test Strip, are substantially equivalent to the INRatio (K020679; K021923) and INRatio2 (K072727) PT/INR Monitoring System and the INRatio PT/INR Test Strip (K092987) currently manufactured and distributed by Alere. The INRatio2 PT/INR Monitoring Systems (Professional and Home) have been verified and validated for ease of use by both Healthcare Professionals and Trained Patients in multiple healthcare professional and patient self-test user clinical trials (K020679; K021923, K072727 and this submission).

Comparison Table of the INRatio/INRatio®2 Monitoring PT/INR Test Systems utilizing the Current INRatio® PT/INR Test Strip *vs.* the Alere™ INRatio®2 PT/INR Test Strip

Parameter	**Current INRatio/INRatio2 PT/INR Monitoring Test Systems utilizing current INRatio PT/INR Test Strip (K020679, K021923, K072727 and K092987)**	**INRatio2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (This submission)**	**Comment/Explanation of difference**
Intended Use	The Alere INRatio/INRatio2 PT/INR Monitoring System is used for the quantitative measurement of Prothrombin Time (PT) in fresh, capillary whole blood. The INRatio/INRatio2 PT/INR Monitoring system is intended for use outside the body (in vitro diagnostic use). The INRatio/INRatio2 PT/INR Monitoring System is intended for professional and home use by people taking warfarin and other oral anticoagulant (blood thinning) therapy who need to monitor the clotting time of their blood. The INRatio/INRatio2 PT/INR Monitoring System is not intended to be used for screening purposes.	*Alere INRatio®2 PT/INR Monitoring System (Professional Use):* The Alere INRatio®2 PT/INR Monitoring System (Professional Use), consisting of the INRatio®2 Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time by health care professionals. The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended to be used for screening purposes. Limitations: The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.	Addition of patient self testing to the intended use of INRatio2 PT/INR Monitoring System

Comparison Table of the INRatio/INRatio®2 Monitoring PT/INR Test Systems utilizing the Current INRatio® PT/INR Test Strip *vs.* the Alere™ INRatio®2 PT/INR Test Strip

Parameter	Current INRatio/INRatio2 PT/INR Monitoring Test Systems utilizing current INRatio PT/INR Test Strip (K020679, K021923, K072727 and K092987)	INRatio2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (This submission)	Comment/Explanation of difference
		Alere INRatio®2 PT/INR Home Monitoring System: The Alere INRatio®2 PT/INR Home Monitoring System, consisting of the INRatio®2 Home Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin therapy on clotting time by properly selected suitably trained users (by prescription for home use or other order of a treating physician). Patients must be stabilized (>6 weeks) on warfarin therapy. The The Alere INRatio®2 PT/INR Home Monitoring System is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Home Monitoring System is not intended to be used for screening purposes.	

Comparison Table of the INRatio/INRatio®2 Monitoring PT/INR Test Systems utilizing the Current INRatio® PT/INR Test Strip *vs.* the Alere™ INRatio®2 PT/INR Test Strip

Parameter	**Current INRatio/INRatio2 PT/INR Monitoring Test Systems utilizing current INRatio PT/INR Test Strip (K020679, K021923, K072727 and K092987)**	**INRatio2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (This submission)**	**Comment/Explanation of difference**
		Limitations: The Alere INRatio®2 PT/INR Home Monitoring System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.	
Intended Users	Healthcare professionals and trained patients on the prescription or other order of a treating physician.	same	Addition of patient self testing to the intended use of the Alere INRatio2 PT/INR Monitoring System
Intended Sample	capillary whole blood	Capillary whole blood	No change
Test Strip Monitor Compatibility	INRatio (professional and patient self test) and INRatio2 (professional) monitors	INRatio2 (professional and patient self-test)	Addition of patient self tesing to the intended use of Alere INRatio2 PT/INR Monitoring System
Mode of Measurement	Electrical Impedance	same	No change
Number of Reaction Sites (and pairs of electrodes)	3 (3 Pairs of Electrodes)	same	No change
Test Strip Layout	"Trident"	same	No change
Quality Control	Integrated in Test Strip	same	No change
	HIGH QC (therapeutic range)	same	No change
	LOW QC (normal range)	same	No change
Test Strip Graphics	Name of product	Name of product and thumbprint	Thumbprint and directional

Comparison Table of the INRatio/INRatio®2 Monitoring PT/INR Test Systems utilizing the Current INRatio® PT/INR Test Strip *vs.* the Alere™ INRatio®2 PT/INR Test Strip

Parameter	**Current INRatio/INRatio2 PT/INR Monitoring Test Systems utilizing current INRatio PT/INR Test Strip (K020679, K021923, K072727 and K092987)**	**INRatio2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (This submission)**	**Comment/Explanation of difference**
		and directional leading arrow	leading arrow graphic added to test strip for ease of use
Minimum Sample Volume	15 µL	9.5 µL	Miniaturized micro-fluidic design of Test Strip channels allows for reduction in minimum sample volume and increases ease of use
Test Time	Approximately 1 min for INRatio2	Approximately 1 min for INRatio2	No change
Measurement Range	INR: 0.7 - 7.5 PT: 7 - 75 sec	INR: 0.7 - 7.5	No change; PT seconds units are no longer reported in package insert; INR units are now industry standard
Reference Range	INR: 0.7 - 1.2 PT: 6.5 - 11.9 sec	INR: 0.8 – 1.3	Reflects verified normal reference range. PT range is no longer reported in package insert; INR units are now industry standard
Strip Calibration	Per WHO889:1999, using normal and therapeutic capillary whole blood samples vs. reference method using normal and therapeutic venous whole blood samples processed to plasma	same	No change
Accuracy	Slope = 0.9 – 1.1 Intercept ± 0.5 INR	Slope = 0.9 – 1.1 Intercept ± 0.5 INR	No change

Comparison Table of the INRatio/INRatio®2 Monitoring PT/INR Test Systems utilizing the Current INRatio® PT/INR Test Strip *vs.* the Alere™ INRatio®2 PT/INR Test Strip

Parameter	**Current INRatio/INRatio2 PT/INR Monitoring Test Systems utilizing current INRatio PT/INR Test Strip (K020679, K021923, K072727 and K092987)**	**INRatio2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (This submission)**	**Comment/Explanation of difference**
Precision (Repeatability)	Normal subjects Capillary %CV - 7.6% Therapeutic Capillary %CV - 5.9%	Normal subjects Capillary %CV - 8.2% Therapeutic Capillary %CV - 6.2% Therapeutic Patient Self Testers Capillary %CV - 5.7%	Minor change; reflects current performance of the test strip
Between Day Precision	Normal Subjects %CV - 8.5%	Not Applicable	No longer reported on package insert as this number is not clinically useful; Between Day Precision can only be determined for normal subjects who are not the intended test population; This is now industry standard
Endogenous Interfering Factors:			
▪ Bilirubin	• None up to 20 mg/dL	▪ None up to 30 mg/dL	• Reflects current performance of the test strip
▪ Hemoglobin/Hemolysis	• None up to 500 mg/dL	▪ None up to 1000 mg/dL	• Reflects current performance of the test strip
▪ Lipemia/triglycerides	• None up to 1500 mg/dL	▪ None up to 1500 mg/dL	• No change
Factor Sensitivity:			
▪ Factor II	• <49% of normal factor level	▪ <56% of normal factor level	• Reflects current performance of the test strip
▪ Factor V	• <61% of normal factor level	▪ <62% of normal factor level	• Reflects current performance

Comparison Table of the INRatio/INRatio®2 Monitoring PT/INR Test Systems utilizing the Current INRatio® PT/INR Test Strip *vs.* the Alere™ INRatio®2 PT/INR Test Strip

Parameter	**Current INRatio/INRatio2 PT/INR Monitoring Test Systems utilizing current INRatio PT/INR Test Strip (K020679, K021923, K072727 and K092987)**	**INRatio2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (This submission)**	**Comment/Explanation of difference**
			of the test strip
▪ Factor VII	▪ <74% of normal factor level	▪ <78% of normal factor level	▪ Reflects current performance of the test strip
▪ Factor X	▪ <72% of normal factor level	▪ <74% of normal factor level	▪ Reflects current performance of the test strip
Exogenous Interfering Factors:			
▪ Fondaparinux	▪ Not previously characterized	▪ Up to 5 mg/L	Further characterization of potential interfering factors; reflects values to appear in labeling
▪ Acetylsalicylic acid	▪ Not previously characterized	▪ Up to 4 mmol/L	
▪ Clopidogrel	▪ Not previously characterized	▪ Up to 20 mg/dL	
▪ Atovastatin	▪ Not previously characterized	▪ Up to 600 µg/L	
▪ Unfractionated Heparin	▪ Not previously characterized	▪ ≥ 2 IU/mL	
▪ Low molecular weight Heparin	▪ Not previously characterized	▪ ≥ 3 IU/mL	
Hematocrit range	30 - 55%	25 – 53%	Expanded range on low end to include a larger patient population; decreased range on upper end. Accuracy was established up to 55% HCT
Operating conditions:			
▪ Temperature	▪ 10 - 35°C (50 - 95°F)	▪ 10 - 32°C (50 - 90°F)	▪ Reflects current performance of the system (monitor and strip)
▪ Humidity	▪ 10% - 95% RH	▪ 15% - 90% RH	

Comparison Table of the INRatio/INRatio®2 Monitoring PT/INR Test Systems utilizing the Current INRatio® PT/INR Test Strip *vs.* the Alere™ INRatio®2 PT/INR Test Strip

Parameter	**Current INRatio/INRatio2 PT/INR Monitoring Test Systems utilizing current INRatio PT/INR Test Strip (K020679, K021923, K072727 and K092987)**	**INRatio2 PT/INR Monitoring System utilizing modified Alere™ INRatio®2 PT/INR Test Strip (This submission)**	**Comment/Explanation of difference**
			▪ Reflects current performance of the system (monitor and strip)
Strip Storage conditions: ▪ Refrig ▪ Room Temp	▪ 35-45°F (2-8°C) until expiration date ▪ Below 90°F (32°C) until expiration date	▪ 35-50°F (2-10°C) until expiration date ▪ Below 90°F (32°C) until expiration date	No change
Strip warm-up time: ▪ Refrig storage ▪ RT storage	▪ 5 min at RT, if stored refrig ▪ N/A, if stored at RT	• same • same	• No change • No change
Strip Stability: ▪ Out of pouch ▪ Pouched	▪ 10 minutes ▪ 15 months at recommended storage conditions	▪ Same ▪ 11 months at recommended storage conditions	▪ No change ▪ Shelf Life at room temperature based on currently available real time stability data

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Alere San Diego, Inc.
c/o Ms. Mara Caler
Regulatory Affairs
9975 Summers Ridge Road
San Diego, CA 92121

MAY 0 1 2012

Re: k110212
Trade/Device Name: Alere INRatio®2 PT/INR Monitoring System (Professional Use); Alere INRatio®2 PT/INR Home Monitoring System; Alere INRatio®2 PT/INR Test Strip
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: April 27, 2012
Received: April 27, 2012

Dear Ms. Caler:

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.

The Office of In Vitro Diagnostic Device Evaluation and Safety has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear under the Indications for Use section of the device's labeling, the patient test report and any promotional materials:

The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

The Alere INRatio®2 PT/INR Home Monitoring System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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).

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

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): k110212

Device Name: Alere INRatio®2 PT/INR Monitoring System (Professional Use),

Indications for Use:

Alere INRatio®2 PT/INR Monitoring System (Professional Use): The Alere INRatio®2 PT/INR Monitoring System (Professional Use), consisting of the INRatio®2 Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin on clotting time by health care professionals. The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended to be used for screening purposes.

Limitations: The Alere INRatio®2 PT/INR Monitoring System (Professional Use) is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

Prescription Use X (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 IF 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) K110212

INDICATIONS FOR USE

510(k) Number (if known): k110212

Device Name: Alere INRatio®2 PT/INR Home Monitoring System

Indications for Use:

Alere INRatio®2 PT/INR Home Monitoring System: The Alere INRatio®2 PT/INR Home Monitoring System, consisting of the INRatio®2 Home Monitor and INRatio®2 PT/INR test strip, is used for quantitative determination of international normalized ratio (INR) in fresh capillary whole blood to monitor the effect of warfarin therapy on clotting time by properly selected suitably trained users (by prescription for home use or other order of a treating physician). Patients must be stabilized (>6 weeks) on warfarin therapy. The The Alere INRatio®2 PT/INR Home Monitoring System is intended for use outside of the body (in vitro diagnostic use). The Alere INRatio®2 PT/INR Home Monitoring System is not intended to be used for screening purposes.

Limitations: The Alere INRatio®2 PT/INR Home Monitoring System is not intended for use in patients who are transitioning from heparin treatment to warfarin therapy.

Prescription Use X (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 IF 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) K110212