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: K072727

OCT 26 2007

A. Submitter:

HemoSense, Inc.
651 River Oaks Parkway
San Jose, CA 95134

Contact: Doug Rundle, VP, QA/RA
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Fax (408) 719-1184
Email: drundle@hemosense.com

Date Prepared: October 18, 2007

B. Device Names:

Classification name	Prothrombin Time Test
Common/usual name	Prothrombin Time Test
Proprietary name	INRatio® 2 PT Monitoring System

C. Predicate Device: INRatio® System, K020679

D. Device Description:

Like the predicate device, the INRatio 2 PT Monitoring System performs a modified version of the one-stage Prothrombin Time test, using a recombinant human thromboplastin reagent. The clot formed in the Prothrombin Time reaction is detected by a change in the electrical impedance of the sample during the coagulation process. The system consists of a monitor, disposable test strips, instruction manual, quick reference guide, training video/DVD, and testing supplies. The monitor measures impedance, heats the test strip to the proper reaction temperature, and provides a user interface. The Test Strips have not been modified from the design described in K020679.

E. Intended Use:

The INRatio 2 PT Monitoring system is used for the quantitative measurement of Prothrombin Time (PT) in fresh, capillary whole blood. The INRatio 2 PT Monitoring system is intended for use outside the body (*in vitro* diagnostic use) by people taking warfarin and other oral anticoagulant (blood thinning) therapy who need to monitor the clotting time of their blood. The INRatio 2 PT Monitoring System is not intended to be used for screening purposes.

F. Comparison with the Predicate Device:

The INRatio 2 PT Monitoring System is a hardware and software modification of the INRatio System. The INRatio 2 and the INRatio have the same intended use and use the same operating principle.

Based on the data and information presented here, the modified INRatio 2 PT Monitoring System is substantially equivalent to the INRatio System currently manufactured and distributed by HemoSense, Inc.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 26 2007

Hemosense, Inc.
C/O Doug Rundle
651 River Oaks Parkway
San Jose, California 95134

Re: k072727
Trade/Device Name: INRatio® 2 PT Monitoring System
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: September 24, 2007
Received: September 26, 2007

Dear Mr. Rundle:

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); 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 Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): K072727

Device Name: INRatio® 2 PT Monitoring System

Indications for Use:

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Prescription Use __X___ (21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use _____ (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K072727