K021922

OCT 24 2002

Appendix F
510(k) Summary

Introduction:	According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.
1. Submitter's name address, contact	HemoSense 600 Valley Way Miilpitas, CA 95035 (408) 719-1393 (phone) (408) 719-1184 (fax) Contact person: Judith Blunt Date prepared: June 10, 2002
2. Device name	Common or Usual Name: Prothrombin Time Test Classification Name: Prothrombin Time Test Trade or Proprietary Name: INRatio
3. Predicate device:	The INRatio System: device for testing Prothrombin Time and INR in whole blood.
4. Device description:	The INRatio Prothrombin Time Monitoring System uses a modified version of the one-stage prothrombin time test. After a drop of blood is applied to the test strip, it is drawn into the test area and mixed with reagents that cause coagulation to begin. The test area on the test strip is separated into three channels, each of which contains electrodes for detection of the blood clot. One channel contains the reagents to perform the prothrombin time test on the blood sample. The other two channels contain the reagents to run control tests. No external quality control tests are required for the INRatio system. The meter monitors the reactions, and calculates the PT and INR for the blood sample, which are reported on the display. If the control results are not within a set range, it indicates a problem with the test and an error message is reported on the display instead of a result. The INRatio is the same as the INRatio, except that the labeling has been modified for readability by the lay user.

5. Intended use:	The INRatio is intended for quantitative prothrombin time testing of fresh, capillary whole blood for monitoring of oral anticoagulation therapy by trained patients or their caregivers, on the prescription or other order of a treating physician.
6. Comparison to predicate device	The INRatio is substantially equivalent in materials, design and intended use to other products that measure Prothrombin Time INR in human blood. Most notably, it is substantially equivalent to the INRatio, manufactured by HemoSense. In fact, it is identical in materials, design and function to the INRAtio, but the labeling has been changed for physician directed, self-test use.
7. Summary of performance data	The INRatio System was found to perform equivalently when used by trained lay users and healthcare professionals. Furthermore, both user populations generated results found to be equivalent to an established reference method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 2 4 2002

Ms. Judith Blunt
Director of Clinical Affairs
HemoSense, Inc.
600 Valley Way
Milpitas, California 95035

Re: k021923
Trade/Device Name: HemoSense INRatio Self-Test PT Monitoring System
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: II
Product Code: GJS
Dated: August 29, 2002
Received: August 30, 2002

Dear Ms. Blunt:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Under Section 522(a) of the act, manufacturers of certain Class II or Class III devices that meet certain criteria may be ordered to conduct Postmarket Surveillance (PS) of that device. We are considering ordering PS for the HemoSense INRation Self-Test System. Please contact Valerie Dada at 301-594-1243 within 15 days of receipt of this letter to arrange a meeting to discuss the objective and design of a PS plan for your device."

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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Appendix G. Indications for Use Statement

June 10, 2002

PREMARKET NOTIFICATION
INDICATIONS FOR USE STATEMENT
(As required by 21 CFR 807.87(j))

510(K) Number: K021923

Device Name: HemoSense INRatio PT Monitoring System

The HemoSense INRatio is an in vitro diagnostic system that provides a quantitative prothrombin time results, expressed in seconds and as an International Normalized Ratio (INR). It uses fresh capillary whole blood and is intended for is intended for quantitative prothrombin time testing of fresh, capillary whole blood for monitoring of oral anticoagulation therapy by trained patients or their caregivers, on the prescription or other order of a treating physician.

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED

Signed: Judith Blunt

Name: Judith Blunt

Position: Director of Clinical Affairs and Product Support

Date: June 10, 2002

Josephine Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021923

Prescription ✓
Home-use