

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

**A. 510(k) Number:**

K072727

**B. Purpose for Submission:**

Special 510(k) for hardware and software modifications

**C. Manufacturer and Instrument Name:**

HemoSense, INC

**D. Type of Test or Tests Performed:**

Prothrombin Time Test

**E. System Descriptions:**

1. Device Description:

The INRatio 2 PT Monitoring System consists of a monitor, disposable test strips, user guide, quick reference guide, training video/DVD, and testing supplies.

2. Principles of Operation:

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.

3. Modes of Operation:

Manual mode.

4. Specimen Identification:

Manual input

5. Specimen Sampling and Handling:

Capillary blood is added directly to the test strip

6. Calibration:

Factory calibration. The monitor performs self-checks at start-up and throughout the testing process.

7. Quality Control:

On board bi-level controls

8. Software:

FDA has reviewed applicant's Hazard Analysis and Software Development processes for this line of product types:

Yes X or No \_\_\_\_\_

**F. Regulatory Information:**

1. Regulation section:

21 CFR 864.7750

2. Classification:

Class II

3. Product code:

GJS

4. Panel:

81 Hematology

**G. Intended Use:**

1. Indication(s) for 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.

2. Special Conditions for Use Statement(s):

#### **H. Substantial Equivalence Information:**

1. Predicate Device Name(s) and 510(k) numbers:

HemoSense INRatio (K020679)

2. Comparison with Predicate Device:

<b>Similarities</b>		
Item	Device	Predicate
Intended Use	Quantitative measurement of prothrombin time in fresh capillary whole blood	same
Sample Volume	15 ul	same
QC	Onboard bi-level controls	same

<b>Differences</b>		
Item	Device	Predicate
Memory	120 tests	60 tests
Software- Access	From various buttons	Only from Menu button
Software – Printing capability from memory	No capability	Able to
Display Screen	LCD, FSTN, 44mmH x 58 mmW	LCD, 128 x 64 matrix
Device size	5.9”H x 2.9” W x 1.8” D	6.2”H x 3” W x 2.25” D

#### **I. Special Control/Guidance Document Referenced (if applicable):**

#### **J. Performance Characteristics:**

1. Analytical Performance:

*a. Accuracy:*

*b. Precision/Reproducibility:*

*c. Linearity:*

*d. Carryover:*

*e. Interfering Substances:*

2. Other Supportive Instrument Performance Data Not Covered Above:

As required for a Special 510(k), the Sponsor has provided a risk analysis as well as a Declaration of Conformity with Design Controls indicating that development activities were conducted under appropriate design controls procedures, and the overall product specifications were met.

**K. Proposed Labeling:**

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

**L. Conclusion:**

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