## 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: K092987

**A. Submitter:**

Biosite Incorporated, an Inverness Medical Innovations Company
9975 Summers Ridge Road
San Diego, CA 92121 USA

Contact: Karin A. Hughes, Ph.D.
Director, Regulatory Affairs
Telephone: 858.805.3628
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Email: khughes@biosite.com

JUN 11 2010

Date Prepared: April 13, 2010

**B. Device Names:**

| | |
|---|---|
| Classification name | Prothrombin Time Test |
| Common/usual name | Prothrombin Time Test |
| Proprietary name | INRatio Test Strips |

**C. Predicate Device:** INRatio2 System, K072727

**D. Device Description:**

The INRatio/INRatio2 Test Strips perform 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 and disposable test strips. The monitor measures impedance, heats the test strip to the proper reaction temperature, and provides a user interface. The blood sample is applied to the Test Strip and the clotting reaction occurs on the Test Strip.

**E. Intended Use:**

The INRatio/INRatio2 PT Monitoring System is used for the quantitative measurement of Prothrombin Time (PT) in fresh, capillary whole blood. The INRatio/INRatio2 PT Monitoring system is intended for use outside the body (*in vitro* diagnostic use). The INRatio/INRatio2 PT 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 Monitoring system is not intended to be used for screening purposes.

The INRatio and INRatio2 PT Monitoring Systems consist of the INRatio or INRatio2 Monitor and the INRatio Test Strips.

## F. Comparison with the Predicate Device:

The modified INRatio/INRatio2 Test Strips are substantially equivalent to the previously cleared INRatio Test Strips (K072727 and Add-to-File, Sept. 24, 2007) currently marketed and distributed by Biosite Incorporated. The modified INRatio/INRatio2 Test Strips are a labelling/performance claims modification of the current INRatio Test Strips.

## G. Nonclinical Data:

Performance testing verified that the modified INRatio/INRatio2 Test Strips have equivalent or better performance compared to the previously cleared INRatio Test Strips with respect to within-day precision, accuracy, heparin sensitivity, factor sensitivity, and potential interferents.

## H. Clinical Data

Clinical data are not presented in this submission; no clinical validation testing was performed for this submission, per discussions with the reviewer.

## I. Conclusions Drawn from Testing

Based on the data and information presented here, the INRatio/INRatio2 Test Strips are substantially equivalent to the INRatio Test Strips currently manufactured and distributed by Biosite Incorporated.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

**Food and Drug Administration**
**10903 New Hampshire Avenue**
**Document Mail Center-WO66-G609**
**Silver Spring, MD 20993-0002**

Biosite Incorporated
c/o Karin A. Hughes, Ph.D.
Director, Regulatory Affairs
9975 Summers Ridge Road
San Diego, CA 92121

**JUN 11 2010**

Re: k092987
INRatio/INRatio2 Test Strips
Regulation Number: 21 CFR 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: Class II
Product Code: GJS
Dated: April 13, 2010
Received: April 13, 2010

Dear Dr. Hughes:

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,

Reena Philip

for Maria M. Chan, PhD
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): K092987

Device Name: INRatio/INRatio2 Test Strips

Indications for Use:

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

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

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K092987