

JAN 26 2009

510(k) Summary for

Berichrom™ Heparin LMW Calibrator

Berichrom™ Heparin LMW Control 1

Berichrom™ Heparin LMW Control 2

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 K083159

A Manufacturer's Name, Address, Contact Information, and Date of Preparation

1 Manufacturer

Siemens Healthcare Diagnostics Products GmbH

Emil-von-Behring Str 76

35041 Marburg, Germany

2 Contact Information

Siemens Healthcare Diagnostics Inc

500 GBC Drive

Newark, Delaware 19702

Attention Janet Fose, Regulatory Affairs Specialist

Telephone 302-631-8826, Fax 302-631-6299

3 Preparation Date October 24, 2008

B Name of Device(s)

Berichrom Heparin LMW Calibrator

Berichrom Heparin LMW Control 1

Berichrom Heparin LMW Control 2

Siemens Healthcare Diagnostics Inc
510(k) Notification
Benchrom™ Heparin LMW Calibrator
Benchrom™ Heparin LMW Control 1
Benchrom™ Heparin LMW Control 2

C Regulatory Information.

- | | |
|---------------------------|---|
| 1 CFR Section(s) | 864 5425 - MULTIPURPOSE SYSTEM FOR IN VITRO COAGULATION STUDIES |
| 2 Classification(s) | Class II |
| 3 Classification Panel(s) | Hematology (81) |
| 4 Product Code(s) | JPA, GIZ, GGC |

D Predicate Device(s)

Calibration Plasma LMW Heparin – K030964

Control Plasma LMW Heparin – K030965

E Device Description(s)

Benchrom Heparin LMW Calibrator

Benchrom Heparin LMW Calibrator is a lyophilized product containing low molecular weight (LMW) heparin from porcine intestine and buffered human plasma. Each package contains 6 vials, each vial requires reconstitution with 1.0 mL distilled or deionized water.

Benchrom Heparin LMW Control 1

Benchrom Heparin LMW Control 1 is a lyophilized, low level, assayed control containing low molecular weight (LMW) heparin from porcine intestine and buffered human plasma. Each package contains 6 vials, each vial requires reconstitution with 1.0 mL distilled or deionized water.

Benchrom Heparin LMW Control 2

Benchrom Heparin LMW Control 2 is a lyophilized, high level, assayed control containing low molecular weight (LMW) heparin from porcine intestine and buffered human plasma. Each package contains 6 vials, each vial requires reconstitution with 1.0 mL distilled or deionized water.

F Device Intended Uses

Benchrom Heparin LMW Calibrator

For the calibration of the Benchrom Heparin assay for measurement of low molecular weight (LMW) heparin.

Benchrom Heparin LMW Control 1

For use as a low level assayed control for the quantitative measurement of low molecular weight (LMW) heparin with the Benchrom Heparin assay.

Siemens Healthcare Diagnostics Inc
510(k) Notification
Benchrom™ Heparin LMW Calibrator
Benchrom™ Heparin LMW Control 1
Benchrom™ Heparin LMW Control 2

Benchrom Heparin LMW Control 2

For use as a high level assayed control for the quantitative measurement of low molecular weight (LMW) heparin with the Benchrom Heparin assay

G Substantial Equivalence Information

The Benchrom Heparin LMW Calibrator, like the Calibration Plasma LMW Heparin, is intended for the calibration of low molecular weight (LMW) heparin. Both the proposed device and the predicate also share similarities in form, matrix and traceability.

The Benchrom Heparin LMW Control 1 and Benchrom Heparin LMW Control 2 are substantially equivalent to Control Plasma LMW Heparin. The Benchrom Heparin LMW Control 1 and Benchrom Heparin LMW Control 2 like, the Control Plasma LMW Heparin are assayed quality control materials and are intended for the measurement of LMW heparin in the low and high concentration range, respectively. Both the proposed devices and the predicate also share similarities in form, matrix and traceability.

H Conclusion

Based on the information provided, the proposed devices, the proposed devices are substantially equivalent to their respective predicate devices.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Siemens Healthcare Diagnostics, Inc
c/o Ms Janet M Fose
Regulatory Affairs Specialist
500 GBC Drive, M/S 514
P O Box 6101
Newark, DE 19714

JAN 26 2009

Re k083159

Trade/Device Name Berichrom Heparin LMW Calibrator
Berichrom Heparin LMW Control 1
Berichrom Heparin LMW Control 2

Regulation Number 21 CFR 864 5425

Regulation Name Multipurpose System for In Vitro Coagulation Studies

Regulatory Class Class II

Product Code JPA, GGC, GIZ

Dated October 24, 2008

Received October 27, 2008

Dear Ms Fose

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

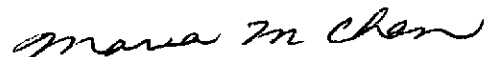
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies You must comply with all the Act's 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

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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" (21 CFR 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,



Maria M. Chan, Ph.D.
Acting Division 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): K083159

Device Name:

Berchrom Heparin LMW Calibrator

Indications for Use:

Berchrom Heparin LMW Calibrator is an *in vitro* diagnostic product used for the calibration of the Berchrom Heparin assay for measurement of low molecular weight (LMW) heparin

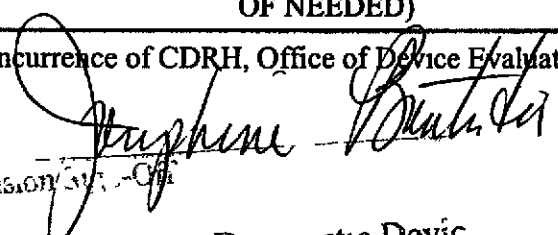
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k)

K083159

Indications for Use

510(k) Number (if known): *K083159*

Device Name.

Benchrom Heparin LMW Control 1

Indications for Use:

Benchrom Heparin LMW Control 1 is an assayed, low level, quality control material for assessment of precision and analytical bias in the quantitative determination of low molecular weight (LMW) heparin with the Benchrom Heparin assay

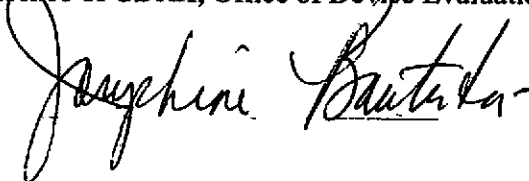
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



Office of In Vitro Diagnostic Device
Evaluation and Research

K 083159 _____

Indications for Use

510(k) Number (if known): *K083159*

Device Name:

Berichrom Heparin LMW Control 2

Indications for Use:

Berichrom Heparin LMW Control 2 is an assayed, high level, quality control material for assessment of precision and analytical bias in the quantitative determination of low molecular weight (LMW) heparin with the Berichrom Heparin assay

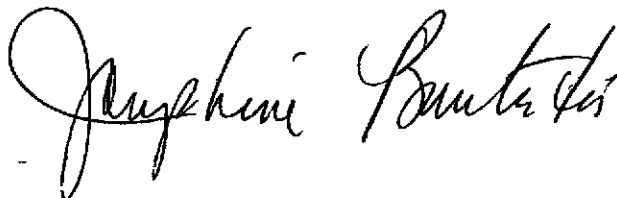
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



Director of the Division of *Medical Devices*
Center for *Medical Devices*

K083159 _____