MAR 17 2005

K043451

Summary Report For Biophen Plasma Calibrator

Description:

BIOPHEN Plasma Calibrator reagent is composed of citrated normal human plasma, lyophilised in the presence of additives and preservatives. Each kit contains 12 vials of lyophilised reagent to be reconstituted with 1 ml distilled water.

Proprietary Name: Biophen Plasma Calibrator

Established Name: Plasma Calibrator

Intended use:

The Biophen plasma calibrator is used as a calibrator in the assay for the determination of several coagulation factors such as Antithrombin III & Protein C. It can be also used as normal human plasma control.

The following table shows various parameters, which are measured using the assays from Hyphen Biomed or from other manufacturers as per the package inserts:

Assays	Reagents	Manufacturers	Reference
ATIII	Biophen Antithrombin	Hyphen Biomed	221102 221105
Protein C	Biophen Protein C	Hyphen Biomed	221202 221205
Lupus Anticoagulant	DWtest® DWconfirm®	American Diagnostica	810 815/815L

DWtest, DWconfirm are registered trade marks from American Diagnostica Inc.

The Biophen Plasma Calibrator is tested for the absence of Lupus Anticoagulant and can be used for this investigation.

Matrix Base: Stabilized reagent from human plasma

Form: Lyophilized

Volume: 1ml per vial

Composition:

Normal human citrated pooled plasma:
Freeze dried powder containing human plasma >75%
Hepes <10 mg
Glycine < 25 mg
Ciprofloxacin <0.001%

Biophen Normal and Abnormal Control Plasma Summary

(Summary of Safety and Effectiveness)

Submitted by:

Hyphen Biomed
95000 Neuville sur Oise, France
Phone # 01 34 40 6510
Fax# 01 34 487236

Contact Person:

Dr. Jean Amiral, President &Scientific Director
jamiral@hyphen-Biomed.com

Summary prepared by:

16th November 2004

Name of the device:

Biophen Normal Control Plasma
&
Biophen Abnormal Control Plasma

Classification Name:

Plasma Controls, Normal and Abnormal

Regulation#: 864.5425

Predicate Device Information:

Plasma Control N (K001256) for Biophen Normal Control Plasma
Lyphochek® Hemostasis Control (K020878) for Biophen Abnormal Control Plasma

Description of the Device/intended use:

Biophen Normal and Abnormal Control Plasma is a set of 12 vials each of normal citrated human plasma used as quality control of some coagulation factors.

The following table shows the various parameters which are measured using assays from Hyphen Biomed or from other manufacturers, and as per the package inserts:

Assays	Reagents	Manufacturers	Reference
ATIII	Biophen ATIII	Hyphen Biomed	221102 221105
Protein C	Biophen Protein C	Hyphen Biomed	221202 221205
Lupus Anticoagulant	DWtest® DWconfirm®	American Diagnostica	810 515/815L

The Biophen Normal and Abnormal Control Plasma are tested for the absence of Lupus Anticoagulant and can be used as a negative control for this investigation.

The Normal control plasma is also tested for the absence of Activated Protein C resistance (Act PC-r). When the APTT is performed with or without Activated Protein C (APC) the ratio obtained (APTT + APC/APTT) is ≥2.00.

Statement of how the technological Characteristics of the device compare to the Predicate device:

Biophen Normal control uses the same principle as the predicate Control Plasma N and is substantially equivalent in performance, intended use and safety and effectiveness.
Biophen Abnormal control uses the same principle as the predicate Lyphockek®Hemostasis Control and is substantially equivalent in performance, intended use and safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 17 2005

HYPHEN Biomed
c/o Mr. Ola Anderson
President
Aniara
9944 Benningtan Drive
Cincinnati, Ohio 45241

Re: k043451
Trade/Device Name: Biophen Normal Control Plasma,
Biophen Abnormal Control Plasma and
Biophen Plasma Calibrator
Regulation Number: 21 CFR § 864.5425
Regulation Name: Multipurpose Systems for In Vitro Coagulation Studies
Regulatory Class: II
Product Code: GGN
Dated: February 14, 2005
Received: February 16, 2005

Dear Mr. Anderson:

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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

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

Enclosure

Indication for use

510(k) number: K043451

Device Name: Biophen Plasma Calibrator

Indication for Use:

Biophen Plasma Calibrator is normal citrated human plasma used as the calibrator in the assay methods for coagulation factors Antithrombin III and Protein C.

The following table shows various parameters which are measured using the assays from Hyphen BioMed or from other manufacturers as per the instructions in the package insert:

Assays	Reagents	Manufacturers	Reference
ATIII	Biophen Antithrombin	Hyphen Biomed	221102 221105
Protein C	Biophen Protein C	Hyphen Biomed	221202 221205
Lupus Anticoagulant	DWtest® DWconfirm®	American Diagnostica	810 815/815L

DWtest, DWconfirm are registered trade marks from American Diagnostica Inc.

The Biophen Plasma Calibrator is tested for the absence of Lupus Anticoagulant and can be used for this investigation.

Prescription Use ✔ And/or Over -The Counter use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

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Division Sign-Off

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Eva

510(k) K043451

Indications for Use

510(k) Number (if known): 043451

Device Name: Biophen Normal Control Plasma &
Biophen Abnormal Control Plasma

Indications for Use:

Biophen Normal and Abnormal Control Plasma is a set of 12 vials each of normal citrated human plasma used as quality control of some coagulation factors.

The following table shows the various parameters which are measured using assays from Hyphen Biomed or from other manufacturers, and as per the package inserts:

Assays	Reagents	Manufacturers	Reference
ATIII	Biophen ATIII	Hyphen Biomed	221102 221105
Protein C	Biophen Protein C	Hyphen Biomed	221202 221205
Lupus Anticoagulant	DWtest® DWconfirm®	American Diagnostica	810 815/815L

DWtest, DWconfirm are registered trade marks from American Diagnostica Inc.

The Biophen Normal and Abnormal Control Plasma are tested for the absence of Lupus Anticoagulant and can be used as a negative control for this investigation.

This control plasma is also tested for the absence of Activated Protein C resistance (Act PC-r). When the APTT is performed with or without Activated Protein C (APC), the ratio obtained (APTT + APC/APTT) is ≥ 2.00 for the Normal Control Plasma.

Prescription Use ✔ (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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K043451