DEC 2 3 2005

510(K) Summary

Biophen Protein C 5 & 2.5

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 K050365

Submitters name & Address: HyphenBiomed
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Contact Name: Dr. Jean Amiral
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Preparation date: 18th Nov 2004

Device name & Classification: Test, qualitative and quantitative factor deficiency

Class: II

Product Code: GGP

Regulation number: 864.7290

Predicate device name: Coamatic Protein C

Manufacturer of Predicate device: Chromogenix AB/Instrumentation Laboratory
Taljegardsgatan 3
S-431 53 Molndal
Sweden, SW

Device Description: Biophen Protein C is a chromogenic assay consisting of chromogenic substrate and Protein C activator.

Device Intended Use: Biophen Protein C is intended for use as a chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.

Performance of the Device:
The following table shows the performance of the device.

Sample	Protein C Concentration%	Intra-Assay CV%	N	Inter Assay CV%	N
Sample 1	98	0.37	9	1.26	12
Sample 2	59	1.17	10	1.97	12
Sample 3	39	0.84	10	1.51	12

Comments on substantial equivalence:

Biophen Protein C is substantially equivalent to Coamatic Protein C (K922201), manufactured by Chromogenix AB, and currently marketed in the United states by Instrumentation laboratory; this is based on the following similarities:

1. Both products are intended for use in the quantitative determination of Protein C activity in citrated human plasma.
2. Both the device uses similar reagents (protein activator and substrate)
3. The reagents used in both the device are in lyophilized form and reconstituted in distilled water.
4. Both devices produce results in % activity of protein C.

The following table shows comparison table of Biophen Protein C and its predicate device.

Comparison of Biophen Protein C & Coamatic® Protein C devices

	Biophen Protein C	**Coamatic ® Protein C (K922201)**
Intended Use	Biophen ProteinC kit is intended for measuring the Protein C Activity in human plasma by chromogenic assay using a manual or an automated method.	Coamatic Protein C is intended for use as a chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.
Indication for Use	Biophen ProteinC kit is intended for measuring the Protein C Activity in human plasma by chromogenic assay using a manual or an automated method.	Coamatic Protein C is intended for use as an in vitro chromogenic assay for the quantitative determination of Protein C activity in citrated human plasma.
Material	Biophen Protein C kit consists of c. Protac®: d. SaPC-21 Substrate Reagent 1 (Protac®): This is highly purified enzyme, extracted from the Agkistrodom C Contortrix snake venom, lyophilized and stabilized, able to specifically activate protein C Reagent 2 (SaPC-21 Substrate):Chromogenic substrate, lyophilized and specific for Protein C Sequence: p-Glu-Pro-Arg-pNa.HCl Purity: 95% Molecular weight: 502.5Kd Free pNa: 0.0%	Coamatic protein C kit consists of 3. Protein C activator 4. Substrate S-2366 Reagent 1 (Protein C activator): Lyophilized venom enzyme with bovine serum albumin(stabilizer) and Ciprofloxacin(preservative) from southern copperhead snake manufactured by Agkistrodom C Contortrix . Reagent 2(S-2366): Lyophilized chromogenic substrate pyroGlu-Pro-Arg-pNA-HCl.
Format	Lyophilized	Lyophilized
Matrix	Reagent 1: Protac® in distilled water matrix Reagent 2: SaPC-21 Substrate in distilled water matrix	Reagent 1: Protein C activator in distilled water matrix Reagent 2: S-2366 Substrate in distilled water matrix
Analytes	Protein C activity	Protein C activity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Hyphen Biomed
c/o Mr. Ola Anderson
US Agent, Aniara
6560 Gove Ct.
Mason, OH 45040

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Re: k050365
Trade/Device Name: Biophen Protein C 5 and 2.5
Regulation Number: 21 CFR 864.7290
Regulation Name: Factor deficiency test
Regulatory Class: Class II
Product Code: GGP
Dated: February 14, 2005
Received: February 15, 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 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.

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 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

Indications for Use

510(k) Number (if known): K050365

Device Name: Biophen ® Protein C 2.5 & 5

Indications for Use:

Biophen Protein C 5 & 2.5 kit is a Chromogenic assay for measuring the Protein C Activity in human citrated plasma using a manual or an automated method.

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)

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Josephine Bautista

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K050365