NOV - 7 2005

Section Q. Biophen Antithrombin – 510(k) Summary (Summary of Safety and Effectiveness)

Submitted by:

Hyphen Biomed
95000 Neuville sur oise, France
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Contact Person:

Dr. Jean Amiral, President & Scientific Director

Summary prepared by:

14th Oct 2004

Name of the Device:

Biophen Antithrombin

Classification Name:

Antithrombin III Assay, Class II

Regulation # 864.7060

Product Code: 81JBQ

Identification of Predicate device:

K 915083 Coamatic ® Antithrombin (Originaly named Coamatic Antithrombin)

Description of the Device/Intended use:

Biophen Antithrombin 2.5 and 5 kit, an in vitro diagnostic test for the quantitative determination of Antithrombin in human plasma to monitor the Antithrombin concentration in human plasma, in instances of recurrent thrombosis resulting from a congenital or acquired deficiency of Antithrombin.

Statement of How the technological Characteristics of the Device Compare to the Predicate Device:

Biophen Antithrombin uses the same principle as the predicate Coamatic® Antithrombin and is substantially equivalent in performance, intended use and safety and effectiveness.

Summary of performance Data:

The assay performance of Biophen Antithrombin was compared to Coamatic ® Antithrombin using plasma received from hospital on automated BCS. The

correlation was 0.99 between the results obtained with the two devices. Overall 21 samples were tested on both the devices.
The intra-assay and Inter assay reproducibility's obtained for samples with variable Antithrombin concentration on ACL is given below:

sample	AT concentration %	Intra Assay (CV %)	N	Inter –Assay (CV %)	N
1	109	0.73%	10	2.57%	12
2	69	0.66%	10	2.49%	12
3	51	0.92%	10	3.72%	12

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV - 7 2005

HYPHEN Biomed
c/o Mr. Ola Anderson
President
Aniara Corporation
6560 Gove Court
Mason, Ohio 45040

Re: k043007
Trade Name: Biophen® Antithrombin 2.5 and Biophen® Antithrombin 5
Regulation Number: 21 CFR § 864.7060
Regulation Name: Antithrombin III Assay
Regulatory Class: II
Product Code: JBQ
Dated: September 14, 2005
Received: September 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 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

Indications for Use

510(k) Number (if known): 043007

Device Name: Biophen ® Antithrombin 2.5 &5

Indications for Use:

BIOPHEN Antithrombin 2.5 and 5 kit, is an in vitro diagnostic test for the quantitative determination of Antithrombin in human plasma, as an aid in the diagnosis of thrombophilia (a congenital deficiency of Antithrombin).

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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K043007

Page 1 of 1