JUL 2 3 2002

vital scientific

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510(k) Summary

Coagulation Control Level 1, 2, 3

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 510K number is: K022046

Applicant: Vital Scientific NV
One Gateway Center, Suite 415
Newton, MA 02158
Phone: 1-617-527-9933 x41
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Contact: Israel M. Stein MD

Date: June 18, 2002

Device Name:
Coagulation Control Level 1, 2, 3 (Coagulation Control Plasma). The Coagulation Control is also tradenamed the Vital Scientific Coagulation Control, and Quikcoag Coagulation Control. References in this document submission may use any of these names interchangeably.

Common Name:
Coagulation Control Plasma

Classification Name:
Coagulation Control Plasma has been classified as Class II device, 21 CFR 864.5425 (Product Code GGN). This device is intended for clinical use as a

control to monitor coagulation testing of Prothrombin Time (PT) and activated Partial Thromboplastin time (APTT).

Description of the Coagulation Control

The Coagulation Control Levels 1, 2 and 3 are lyophilized preparations of citrated plasma obtained from healthy donors, which are adjusted to yield prolonged PT and APTT values. Prior to lyophilization buffer and a stabilizer are added. The bulk plasma is tested using an FDA approved method for HBsAG, HIV antibodies and HCV antibodies and is certified for negativity for each batch.

Intended Use

The Coagulation Controls Levels 1, 2, and 3 are intended for clinical use as a control to monitor the performance of coagulation testing of Prothrombin Time (PT) and activated Partial Thromboplastin time (APTT). Level 1 yields result in the normal range. Level 2 yields results in the moderately abnormal range. Level 3 is intended to yield results in the extremely abnormal range.

Labeling:

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence:

The Coagulation Control Level 1 was compared to Precision Biologic Pooled Normal Plasma (K952662). The Coagulation Control 2 was compared with the Assess Low Abnormal Control from Instrumentation laboratory (K931117). The Coagulation Control 3 was compared with the Assess High Abnormal Control from Instrumentation Laboratory (K931118) on the MLA-900C Coagulometer (K884863).

Within-run precision studies were performed and yielded substantially equivalent data as summarized in Tables 1 and 2 below.

Table 1: Within-run Precision Results using PT Reagents

Control Level	PT Vital Controls Average ± %CV, n = 20	PT Reference Controls Average ± %CV, n = 20
Level 1 (Normal)	12.0 ± 1.1%	**11.6 ± 0.7%**
Level 2 (Low abnormal)	18.8 ± 1.4%	**18.7 ± 1.2%**
Level 3 (High abnormal)	32.6 ± 3.5%	**32.6 ± 2.7%**

Table 2: Within-run Precision Results using APTT Reagents

Control Level	**APTT values of Vital Controls** Average ± %CV, n = 20	APTT values of Reference Controls Average ± %CV, n = 20
Level 1 (Normal)	28.5 ± 2.3%	**24.9 ± 2.3%**
Level 2 (Low abnormal)	47.0 ± 1.7%	**54.8 ± 2.2%**
Level 3 (High abnormal)	61.2 ± 1.9%	**95.7 ± 2.3%**

Between-run precision studies were performed and yielded substantially equivalent data as summarized in Tables 3 and 4.

Table 3: Day to Day Precision Results using PT Reagent

Day	**PT values of Vital Controls** Average ± %CV			PT values of Reference Controls Average ± %CV		
	Level 1	**Level 2**	**Level 3**	**Normal**	**Low Abnormal**	**High Abnormal**
Average (all days)	**11.9**	**18.3**	**31.8**	**11.5**	**18.3**	**31.6**
%CV (between days)	**1.5%**	**3.5%**	**4.5%**	**1.2%**	**2.0%**	**3.3%**

Table 4: Day to Day Precision Results using APTT Reagent

Day	**APTT values of Vital Controls** Average ± %CV			APTT values of Reference Controls Average ± %CV		
	Level 1	**Level 2**	**Level 3**	**Normal**	**Low Abnormal**	**High Abnormal**
Average (all days)	**28.5**	**46.7**	**61.8**	**25.0**	**54.5**	**94.1**
%CV (between days)	**1.8%**	**0.7%**	**3.9%**	**0.5%**	**2.0%**	**2.7%**

Vital Scientific concludes that the Coagulation Controls Levels 1,2, and 3 have a similar intended use, technological characteristics and performance data which

support the statement that the Coagulation Controls Levels 1,2, and 3 are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 2 3 2002

Israel M. Stein, MD
Managing Director
US Branch OfficeVital Scientific
One Gateway Center
Suite 415
Newton, MA 02158

Re: k022046
Trade/Device Name: Coagulation Control Levels 1, 2, and 3
Regulation Number: 21 CFR 864.5425
Regulation Name: Multipurpose system for in vitro coagulation studies
Regulatory Class: Class II
Product Code: GGN
Dated: June 21, 2002
Received: June 24, 2002

Dear Dr. Stein:

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 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K022046

Device Name: Coagulation Control Levels 1, 2, and 3

Indications For Use:

The Coagulation Controls Levels 1, 2, and 3 are *in-vitro diagnostic* reagents intended for clinical use as a control to monitor the performance of coagulation testing of Prothrombin Time (PT) and activated Partial Thromboplastin time (APTT). Level 1 yields result in the normal range. Level 2 yields results in the moderately abnormal range. Level 3 is intended to yield results in the extremely abnormal range.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Josephini Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices K022046
510(k) Number

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)