NOV 1 2002

vital scientific

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510(k) Summary

Vital Scientific APTT

The assigned 510K number is: K022021

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: October 30, 2002

Device Name:
Vital Scientific APTT (In-vitro diagnostic reagent). The Vital Scientific APTT is also tradenamed the QuikCoag APTT, and APTT. References in this document submission may use these names interchangeably.

Common Name:
Activated Partial Thromboplastin Time (APTT)

Classification Name:
Activated Partial Thromboplastin - has been classified as Class II device, as per 21 CFR 864.7925 (Product Code GFO). This device is intended for clinical use in conjunction with an analyzer to measure clot formation.

Description of the APTT
The APTT reagent is intended for use in determining activated partial thromboplastin time (APTT) and coagulation factor assays that are based on a

modified APTT. The capacity of blood to form a fibrin clot by way of the intrinsic homeostatic pathway requires coagulation factors XII, XI, IX, VIII, platelet lipids and calcium. The assay is performed by the addition of a suspension of rabbit brain cephalin with a surface activator.

Intended Use

The Vital Scientific APTT is an *in-vitro* diagnostic reagent intended for use in a manual method in a clinical laboratory for the performance of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway.

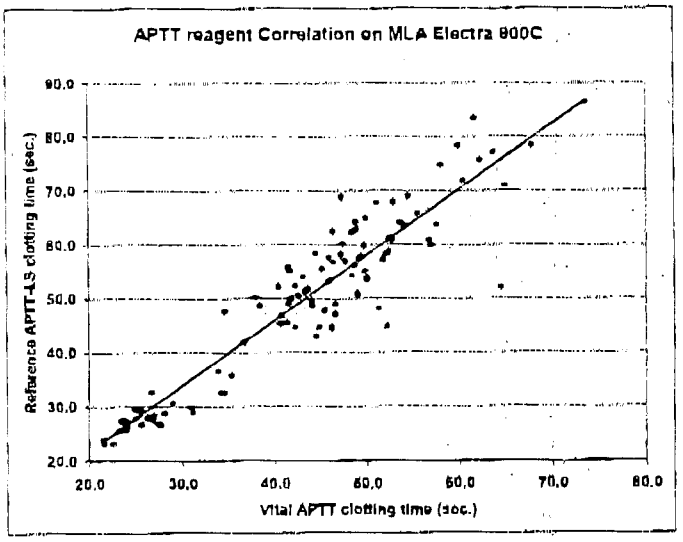
Labeling:

This device is labeled in accordance with 21 CFR 801.

Substantial Equivalence:

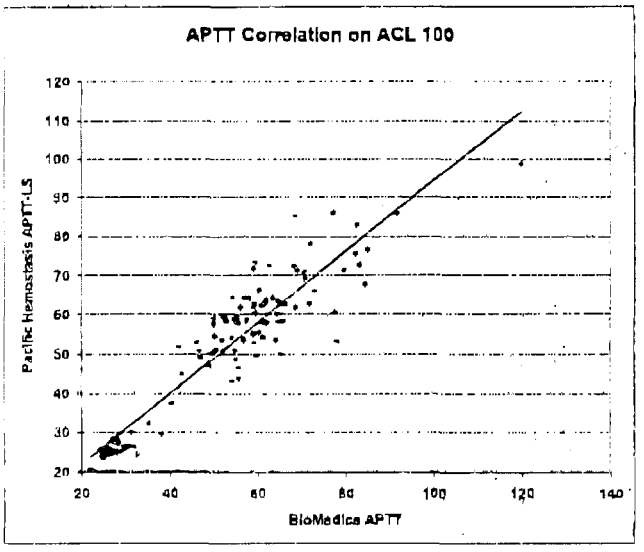
The safety and effectiveness of APTT has been demonstrated by showing its substantial equivalence to APTT-LS manufactured by Fisher Diagnostics (formerly Pacific Hemostasis) K891337.

A correlation study was performed using a total of 107 patient plasmas; 30 from patients with normal APTT values and 77 with patients undergoing heparin therapy. The assays were performed on the MLA 900C coagulometer (K884863). The correlation coefficient for all plasmas was 0.938 and the slope is 0.727 and the intercept is 6.96, indicating acceptable correlation between the two reagents. The results are plotted on the following graph.



A correlation study of these reagents was also performed on an ACL-100 coagulometer (K881367) in the clinical laboratory of a community hospital using

a total of 107 patient plasmas; 30 from patients with normal APTT values and 77 with patients undergoing heparin therapy. The correlation coefficient for all plasmas was 0.930, the slope was 0.952 and the intercept was 3.76, indicating acceptable correlation between the two reagents. The results are plotted on the following graph.



Day to Day and Within-run Precision studies were performed. All within-run %CV values were less than 5 %. The day to day precision is the %CV of the average APTT value obtained over five days. All day to day %CV values were less than 5%. The day to day and within run precision of Vital APTT and the predicate device APTT reagent were equivalent. The results for the within-run precision are shown in Table 1 and for the day to day precision is shown in Table 2 below:

Table 1 Within-run Precision

Controls	Vital APTT		Reference APTT-LS	
	Average (n=16)	% CV	Average (n=16)	%CV
Normal	24.2	1.1 %	25.0	2.3 %
Low Abnormal	43.3	4.3 %	55.0	2.3 %
High Abnormal	73.8	4.3 %	94.7	2.4 %
Average Precision	3.2 %		2.3 %	

Table 2: Day to Day Precision

	Vital APTT		Reference APTT-LS	
	Average	%CV	Average	%CV
Normal Control				
Average (n=5)	24.2	1.4 %	25.0	2.4 %
Day to Day % CV	3.6 %		0.2 %	
Low Abnormal				
Average (n=5)	41.9	2.7 %	54.4	2.1 %
Day to Day % CV	2.5 %		1.9 %	
High Abnormal				
Average (n=5)	70.2	3.3 %	93.8	1.9 %
Day to Day % CV	4.0 %		2.6 %	

Vital Scientific concludes that the APTT has a similar intended use, a similar technological principle, and clinically acceptable performance comparable to similar devices currently in commercial distribution and is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 1 2002

Israel M. Stein, M.D.
Managing Director
Vital Scientific NV
One Gateway Center, Suite 415
Newton, MA 02158

Re: k022021
Trade/Device Name: Vital Scientific APTT
Regulation Number: 21 CFR 864.7925
Regulation Name: Partial Thromboplastin Time Tests
Regulatory Class: Class II
Product Code: GFO
Dated: September 30, 2002
Received: October 3, 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): K022021

Device Name: **Vital Scientific APTT**

Indications For Use:

The Vital Scientific APTT is an *in-vitro* diagnostic reagent intended for use in a manual method in a clinical laboratory for the performance of Activated Partial Thromboplastin Time (APTT) testing for the detection of coagulation abnormalities in the intrinsic pathway.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K022021

Prescription Use ✓ OR Over-The-Counter Use

(Per 21 CFR 801.109) (Optional Format 1-2-96)