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vital scientific

510(k) Summary

Fibron–1 Coagulation Analyzer

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: k021976

Applicant: Vital Scientific NV
One Gateway Center, Suite 415
Newton, MA 02158
Phone: 1-617-527-9933 x41
Fax: 1-617-527-8230

Contact: Israel M. Stein MD

Date: August 22, 2002

Device Name:
Fibron-1 (Coagulation Instrument).

Common Name:
Coagulation Instrument

Classification Name:
Coagulation Instrument has been classified as Class II device, 21 CFR 864.5400 (Product Code KQG). This device is intended for clinical use in conjunction with certain materials to measure a clot formation.

Description of the Fibron-1
The Fibron-1 is a photo-optical instrument used for the performance of in-vitro diagnostic clotting testing of citrated plasma samples in the clinical laboratory. The instrument utilizes photo-optical principles for clot detection. The light source is a high intensity photodiode. The incubator block is temperature regulated to 36.5 - 37.5°C and contains four measuring positions, 4 reagent and 4 cuvette pre-warming positions.

Intended Use

The Fibron-1 is a photo-optical instrument used for the performance of in-vitro diagnostic clotting testing of citrated plasma samples in the clinical laboratory. The Fibrin-1, which uses clot formation as an endpoint, may be used for the performance of the Prothrombin Time Test (PT) and the Activated Partial Thromboplastin Test (APTT).

Substantial Equivalence:

The Fibron-1 is comparable to the MLA-900C (K884863) and the ACL 100 (K881367). The instruments have a similar intended use for in-vitro diagnostic coagulation testing in the clinical laboratory. Further, the proposed device and the predicate devices utilize photo-optical measurement principles for clot detection. The Fibron-1 is also typical of photo-optical coagulation systems in general.

Fibron-1 is a "manual" coagulation instrument, in that the user must pipettes both sample and test reagent. In contrast, the MLA-900C is semi-automated which requires manual sample addition, but has an automatic pipette for reagent addition. The light source for the MLA instruments is a halogen lamp and the wavelength is set at 550 nm for clotting assays. An LED at 620 nm is used by the Fibron-1. Although the Fibron-1 uses a different wavelength for clotting assays compared to the MLA, it has been optimized for this specific light source. The performance data generated support this statement.

Comparison instrument testing was performed in-house and at a community hospital and the results are shown in Tables 1 and 2. Specimens were evaluated from healthy individuals and from patients with different pathological conditions, which are expected to affect the results for a particular assay. Clotting time ranged from 10 to 39 seconds.

Table 1 Instrument to Instrument Correlation with PT Reagent.

Instruments	Parameter	Slope	Intercept	Correlation
Fibron-1 vs ACL 100	Clotting time	1.24	-2.46	**0.972**
Fibron-1 vs ACL 100	INR	1.28	-0.23	**0.969**

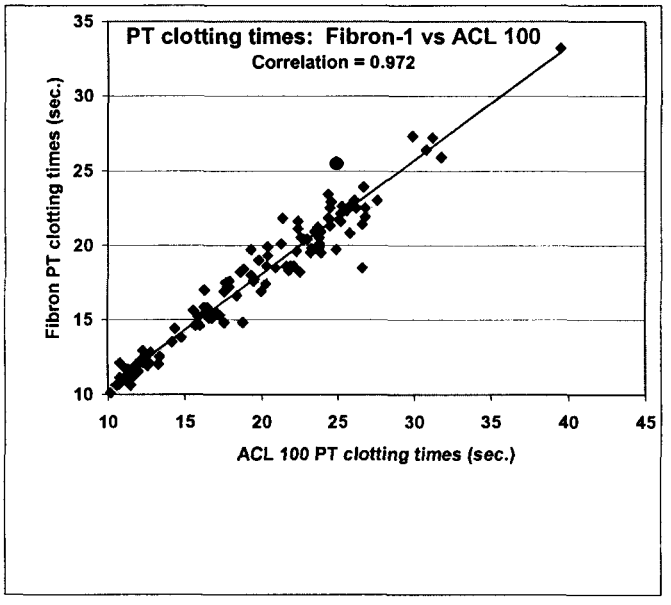
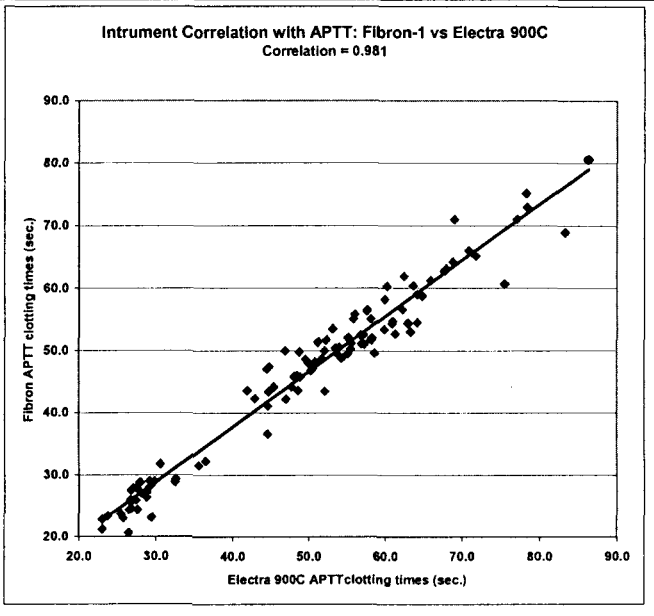


Table 2: Instrument to Instrument Correlation with APTT Reagent.

Instruments	Correlation	Intercept	Slope
Fibron-1 / ACL 100	0.976	6.68	0.763
Fibron-1 / Electra 900C	0.981	2.05	0.892



Within-run and Day–to-Day run precision studies were performed as shown in Tables 3 and 4 which summarize the data obtained from these studies.

Table 3 Within-run Precision

Control	Fibron-1	MLA 900C
Control Level 1 Average ± %CV	12.0 ± 2.0 % (n = 20)	11.5 ± 2.0 % (n = 20)
Control Level 2 Average ± %CV	20.0 ± 1.9 % (n = 19)	18.7 ± 1.2 % (n = 20)

Table 4 – Day-to-Day Precision

Control and Day	Fibron-1 Average ± %CV	MLA 900C Average ± %CV
Normal - Day 1	12.0 ± 2.0 % (n = 20)	11.6 ± 0.7 % (n = 20)
Normal - Day 2	11.0 ± 2.4 % (n = 4)	11.3± 0.4 % (n = 4)
Normal - Day 3	11.6 ± 1.5 % (n = 4)	11.6 ± 1.6 % (n = 3)
Normal - Day 4	11.6 ± 2.1 % (n = 4)	11.4 ± 0.9 % (n = 3)
Normal - Day 5	11.8 ± 1.3 % (n = 4)	11.6 ± 1.8 % (n = 4)
Average ± %CV	**11.6 ± 3.2 %**	**11.5 ± 1.2 %**
Low Abnormal - Day 1	20.0 ± 1.9 % (n = 19)	18.7 ± 1.2 % (n = 20)
Low Abnormal - Day 2	19.1 ± 1.4 % (n = 4)	17.7± 0.7 % (n = 4)
Low Abnormal - Day 3	19.5 ± 1.6 % (n = 4)	18.4 ± 0.6 % (n = 3)
Low Abnormal - Day 4	19.4 ± 1.1 % (n = 4)	18.3 ± 0.3 % (n = 3)
Low Abnormal - Day 5	20.1 ± 1.2 % (n = 4)	18.3 ± 1.4 % (n = 3)
Average ± %CV	**19.6 ± 2.1 %**	**18.3 ± 2.0 %**

Precision and correlation studies were performed for PT and APTT. Tables 5 and 6 summarize the data obtained from these studies.

Table 4

PT	Average %CV of Duplicates	Stand. Dev. Average %CV
Normal Control 18 duplicates	**1.28%**	**1.28%**
Low Abnormal 17 duplicates	**1.12%**	**0.77%**
High Abnormal 18 duplicates	**1.01%**	**0.75%**
All levels 52 duplicates	**1.14%**	**1.14%**

Table 5

APTT	Average %CV of Duplicates	Stand. Dev. Average %CV
Normal Control 18 duplicates	**1.90%**	**1.75%**
Low Abnormal 16 duplicates	**0.86%**	**0.60%**
High Abnormal 18 duplicates	**2.45%**	**2.77%**
All levels 51 duplicates	**1.59%**	**2.03%**

The data for precision and accuracy demonstrate general agreement with levels that are comparable to other systems approved for marketing commercially in the United States. The data demonstrate positive correlation and substantial equivalence.

The Fibron-1 operates in the normal laboratory environment. The product does not support or sustain life and does not present a reasonable risk of illness or injury. When procedures found in the Operations Manual are followed the device is safe in general laboratory use.

Vital Scientific NV, concludes that the Fibron-1 has a similar intended use, technological characteristics and combined performance data which support the statement that the Fibron-1 is substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 25 2002

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

Re: k021976
Trade/Device Name: Fibron-1
Regulation Number: 21 CFR § 864.5400
Regulation Name: Coagulation Instrument
Regulatory Class: II
Product Code: KQG, JBT
Dated: September 18, 2002
Received: September 23, 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): K 021976

Device Name: **Fibron -1**

Indications For Use:

The Fibron-1 is a photo-optical instrument used for the performance of in-vitro diagnostic clotting testing of citrated plasma samples in the clinical laboratory. The Fibrin-1, which uses clot formation as an endpoint, may be used for the performance of the Prothrombin Time Test (PT) and the Activated Partial Thromboplastin Test (APTT).

(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 K021976

Prescription Use OR Over-The-Counter Use

(Per 21 CFR 801.109)

(Optional Format 1-2-96)