K022977

NOV 27 2002

Summary of Safety and Effectiveness Information

Stratus® CS D-dimer CalPak (calibrator)

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR§807.92.

Submitter's Name:	Richard M. Vaught Dade Behring Inc. P.O. Box 6101 Newark, DE 19714-6101
Date of Preparation:	September 4, 2002
Name of Product:	Stratus® CS D-dimer CalPak (calibrator)
FDA Classification Name:	Calibrator (21 CFR§862.1150); DAP
Predicate Device:	VIDAS® D-dimer (DD) Calibrator
Device Description:	The Stratus® CS D-dimer CalPak consists of a plastic cartridge (CalPak) containing human D-dimer in a liquid, buffered bovine protein matrix in each of three wells. The CalPak is designed for use only on the Stratus® CS analyzer
Intended Use:	The Stratus® CS D-dimer CalPak is an *in vitro* diagnostic product used to calibrate the Stratus® D-dimer method on the Stratus® CS STAT fluorometric analyzer.

Comparison to Predicate Device:

	Stratus®CS D-dimer CalPak	VIDAS® D-dimer Calibrator
Intended Use:	Calibration of the Stratus® D-dimer method	Calibration of the VIDAS® D-dimer method
Form:	Liquid, stored frozen	Lyophilized
Matrix:	Buffered bovine protein matrix with human D-dimer, stabilizers and sodium azide	Lyophilized fibrin degradation product from human plasma with glycine-albumin bovine buffer and sodium azide.
Package:	Sealed plastic cartridge for use only on the Stratus® CS analyzer	Vials; 2 mL reconstituted
Calibration:	Calibration curve updated for each lot initially, in triplicate and every 60 days thereafter using Master lot values. After completion of each test, the recovered values are automatically calculated from the stored calibration coefficients.	One point calibration tested in duplicate, with each Master lot initially by the user. Afterwards, the user recalibrates every 14 days.

Comments on Substantial Equivalence:

Both the Dade Behring Stratus® CS D-dimer CalPak and the VIDAS® D-dimer calibrator products are intended to calibrate their respective closed system methods utilizing similar designs consisting of human blood products in a buffered, bovine protein-based matrix.

Conclusion:

The Stratus® CS D-dimer CalPak is substantially equivalent in intended use and design to the VIDAS® D-dimer calibrator as noted above.

RM Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager
September 4, 2002

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Mr. Richard M. Vaught
Regulatory Affairs and Compliance Manager
Dade Behring, Inc.
Chemistry/Immunochemistry
Glasgow Business Community
Bldg. 500, MS 514 P.O. Box 6101
Newark, DE 19714

Re: k022977
Trade/Device Name: Stratus® CS D-dimer CalPak (calibrator)
Regulation Number: 21 CFR 864.7320
Regulation Name: Fibrinogen/fibrin degradation products assay
Regulatory Class: Class II
Product Code: DAP; GHH; JIT
Dated: October 30, 2002
Received: November 15, 2002

Dear Mr. Vaught:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE STATEMENT

Device Name: K022977

Stratus® CS D-dimer CalPak (calibrator)

Indications for Use:

The Stratus® CS D-dimer CalPak is an *in vitro* diagnostic product used to calibrate the Stratus® D-dimer method on the Stratus® CS STAT fluorometric analyzer. This calibrator is intended for medical purposes to establish points of reference that are used in the determination of D-dimer concentration in human specimens.

R M Vaught

Richard M. Vaught
Regulatory Affairs and Compliance Manager

September 4, 2002

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

J P Reeves for J. Bautista

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022977

Prescription Use ✓ **OR** **Over-the-counter Use** _____
(Per 21 CFR 801.109)

(Optional format 1-2-96)