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K020229

FEB 0 6 2002

510(k) Summary
R&D Systems, Inc. BODY FLUID Control

Date of Summary:	January 22, 2002
Company Name:	R&D Systems, Inc. 614 McKinley Place N.E. Minneapolis, MN 55413
Contact name:	Ralph E. Hogancamp 612-656-4413, FAX 612-379-6809
Classification name:	White and Red Blood Cell Control
Product name:	R&D BODY FLUID Control
CFR section:	864.8625 Hematology quality control mixture.
Device Class:	Class II

Predicate Device: Spinalscopics Control, manufactured by Quantimetrix Corporation 2005 Manhattan Beach Boulevard, Redondo Beach, CA 90278-1205.
510(k) number: K970862.

Description: This control is an assay control mixture for hemocytometer counts. R&D BODY FLUID Control is composed of WBCs and RBCs in a stabilizing medium. R&D BODY FLUID Control simulates cells and body fluids in morphology and count.

Intended use: R&D BODY FLUID Control is used to monitor total cell counts performed manually using a hemocytometer to validate the quantitation of red and white cells in patient body fluid samples.

Comparison: Both products are used with manual hemocytometer methods to monitor total cell counts in patient body fluids.

Discussion: Laboratory testing of 3 validation lots have shown R&D BODY FLUID Control to have substantial equavalence in performance, precision and stability to the predicate device. R&D BODY FLUID Control passed the acceptance criteria of remaining within the assay range over the life of the product. R&D BODY FLUID Control has demonstrated precision as indicated by the small standard deviation and %CV's obtained during laboratory testing. Expiriation dating has been established at 14 weeks in customers hands (closed vial) and 30 days, or 14 entries (open vial) when stored at 2 - 8° C and handled according to instructons for use.

Conclusion: R&D BODY FLUID Control is a safe and effective control for the above intended use when used as instructed in the package insert.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB 0 6 2002

Mr. Ralph E. Hogancamp
Quality Specialist
R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413

Re: k020229
Trade/Device Name: R&D BODY FLUID Control
Regulation Number: 21 CFR § 864.8625
Regulation Name: Hematology QC Mixture
Regulatory Class: II
Product Code: JPK
Dated: January 22, 2002
Received: January 23, 2002

Dear Mr. Hogancamp:

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

K020229

Device Name: R&D BODY FLUID Control

Indications for Use:

R&D BODY FLUID Control is used to monitor total cell counts performed manually using a hemocytometer to validate the quantitation of red and white cells in patient body fluid samples.

(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 K020229

Prescription Use ✓ OR Over-The-CounterUse_____

(Optional Format 1-2-96)