R&D SYSTEMS

DEC 10 1998

K984099

## Special 510(k) Summary
# QBC® Centrifugal Hematology Control

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| Date of Summary: | November 16, 1998 |
| Company Name: | R&D Systems, Inc.<br>614 McKinley Place N.E.<br>Minneapolis, MN 55413 |
| Contact name: | Kenneth T. Edds, Ph.D.<br>612-379-2956, FAX 612-379-6580 |
| Classification name: | multiparameter hematology control |
| Classification code: | 81JPK Hematology Control mixtures for Quality Control |
| Product name: | QBC® Centrifugal Hematology Control |
| CFR section: | 864.8625 |
| Device Class: | Class II |

Device to which substantial equivalence is claimed:
QBC® Centrifugal Hematology Control, manufactured by R&D Systems, Inc. and currently being sold by Becton Dickinson Primary Care Diagnostics, Sparks, MD.
510(k) number: K954137

The product is an *in vitro* diagnostic reagent composed of mammalian erythrocytes, mammalian leukocytes and simulated platelets in a plasma-like fluid with preservatives. QBC Control is composed of stable materials that provide a means of monitoring the performance of QBC centrifugal hematology systems. Overall system performance of disposable QBC blood tubes, including tube coating and float, is also monitored. QBC control is available in two levels that have varying concentrations of the parameters measured. QBC Control is used and tested in the same manner as patient samples.

Intended use: QBC Centrifugal Hematology Control is intended as a quality control for QBC+, QBC II, QBC II Plus, QBC Reference and QBC AUTOREAD centrifugal hematology systems, to monitor hematocrit, hemoglobin, white blood cell count, granulocyte count, lymphocyte/monocyte count, and platelet count.

QBC® Centrifugal Hematology Control has an intended use that is similar to the predicate device. The technologies of the two devices are similar.

Nonclinical testing of 3 validation lots centered on the performance attributes of stability and precision. QBC® Centrifugal Hematology Control passed the acceptance criteria of remaining within the assay range over the life of the product. QBC® Centrifugal Hematology Control also demonstrated precision as indicated by the small standard deviations and %CVs obtained during testing. Improved platelet performance was also noted. Expiration dating has been established at 21 days in the customers hands (closed vial) and 8 days open vial when stored at 2-8°C and handled according to instructions for use.

R & D Systems, Inc.
614 McKinley Place N.E. PHONE: (612) 379-2956 WATS: (800) 343-7475
Minneapolis, MN 55413 FAX: (612) 379-6580 E-MAIL: info@rndsystems.com

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 10 1998

Kenneth T. Edds, Ph.D.
Regulatory Affairs
R&D Systems, Inc.
614 McKinley Place N.E.
Minneapolis, Minnesota 55413

Re: K984099
Trade Name: QBC® Centrifugal Hematology Control
Regulatory Class: II
Product Code: JPK
Dated: November 16, 1998
Received: November 17, 1998

Dear Dr. Edds:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

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"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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

510(k) Number: K984099

Device Name:QBC Centrifugal Hematology Control

Indications for Use:
QBC Centrifugal Hematology Control is intended as a quality control for QBC+, QBC II, QBC II Plus, QBC Reference and QBC AUTOREAD centrifugal hematology systems, to monitor hematocrit, hemoglobin, white blood cell count, granulocyte count, lymphocyte/monocyte count, and platelet count.

(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 K984099

✓
Prescription Use_____ OR Over-The-CounterUse_____

(Optional Format 1-2-96)