

SEP 23 1999

**510(k) SUMMARY**

**SUBMITTED BY:** BECTON DICKINSON MICROBIOLOGY SYSTEMS  
7 LOVETON CIRCLE  
SPARKS, MD 21152

**CONTACT:** Monica E. Giguere  
Regulatory Affairs Associate

**TELEPHONE:** (410) 316-4287

**PREPARED:** August 20, 1999

**DEVICE NAME:** QBC STAR™ Centrifugal Hematology System

**PREDICATE  
DEVICE:** QBC™ AUTOREAD™ Plus Hematology System

**INTENDED USE:** The QBC STAR™ Centrifugal Hematology System provides a diagnostic hematology profile on venous or capillary blood: hematocrit, hemoglobin, mean corpuscular hemoglobin concentration (MCHC), platelet count, white blood cell count, granulocyte count (% and number) and lymphocyte/monocyte count (% and number).

## **DEVICE DESCRIPTION:**

The QBC STAR™ Centrifugal Hematology System is a self-contained, whole blood automated hematology system. Testing can be performed on venous or capillary samples. All tests are performed in the QBC STAR™ Blood Collection Tube. The system is powered by a universal voltage internal power supply that plugs directly into an AC power source. The instrument is factory preset and does not require user calibration.

The methodology of the QBC STAR centrifugal hematology system is based on electro-optical linear measurements of the discrete layers of packed blood cells in a microhematocrit-type tube. The cell layering results from density gradients formed during high-speed centrifugation of the blood. Nine primary hematology values, including, hematocrit, hemoglobin, mean corpuscular hemoglobin concentration (MCHC), white blood cell count, platelet count, granulocyte count (% and number) and lymphocyte/monocyte count (% and number) are derived.

QBC hematology tests utilize precision-bore glass tubes pre-coated with potassium oxalate, acridine orange fluorochrome stain and an agglutinating agent. During high-speed centrifugation of the blood-filled tube, the cells form in packed layers, according to their density, around the float, which has descended into the red blood cells. The buffy coat is automatically scanned and fluorescence and absorbance readings are made to identify the expanded layers of differentiated cells. Volumes of these packed cell layers are then computed to obtain quantitative values for the listed parameters.

On the QBC STAR system, the hematocrit, white blood cell counts and the platelet count are direct measurements of the cell layers. The hemoglobin measurement is directly related to the density of the red blood cells and based on the depth of penetration of the float into the red blood cell layer. Mean Corpuscular Hemoglobin Concentration (MCHC) is a function of hemoglobin and hematocrit and is electronically calculated according to the standard equation ( $\text{Hgb}/\text{Hct} \times 100$ ).

**DEVICE COMPARISON:**

The QBC STAR Centrifugal Hematology System is a modification of the QBC AUTOREAD Plus System and is substantially equivalent<sup>1</sup> to it. Table 1 summarizes the similarities and differences between the QBC STAR system and the modified/predicate device.

Table 1: Device Comparison - QBC STAR™ Centrifugal Hematology System vs. QBC™ AUTOREAD™ Plus System

<b>FEATURE</b>	<b>QBC STAR System</b>	<b>QBC™ AUTOREAD™ Plus</b>
Intended Use	The QBC STAR Centrifugal Hematology System provides a diagnostic hematology profile on venous or capillary blood: Hematocrit, Hemoglobin, Mean Corpuscular Hemoglobin Concentration (MCHC), Platelet Count, White blood cell count, Granulocyte (% and number) and Lymphocyte/Monocyte (% and number).	The QBC AUTOREAD Plus System provides a diagnostic hematology profile on venous or capillary blood: Hematocrit, Hemoglobin, Mean Corpuscular Hemoglobin Concentration (MCHC), Platelet Count, White blood cell count, Granulocyte (% and number) and Lymphocyte/Monocyte (% and number).
Methodology	Electro-optical linear measurements of the discrete layers of blood cells in a microhematocrit-type tube.	Electro-optical linear measurements of the discrete layers of blood cells in a microhematocrit-type tube.
Sample Tube	Uses the QBC™ AccuTube enclosed in a plastic sleeve. (a.k.a. QBC STAR™ Blood Collection Tube)	Uses the QBC™ AccuTube. It is not enclosed in a plastic sleeve.
Float	Injection molded polystyrene plastic	Injection molded polystyrene plastic
Float Insertion	Inserted by user during capping operation.	Inserted by user as a distinct step.
Fill Volume	70µL ± 5µL	70µL ± 5µL
Closed-end stopper	Polyethylene plug with small air vent hole that does not require specific plug seating step by the user. The extruded plug has a fluorescent dye additive so the bottom of the red blood cells can be located.	Santoprene plug with molded-in vents that must be seated by the user. The injection-molded plug also uses a fluorescent dye additive so the bottom of the red blood cells can be located.

<sup>1</sup> The term “substantial equivalence” as used in this 510(k) notification is limited to the definition of substantial equivalence as found in the Federal Food, Drug and Cosmetic Act, as amended and as applied under 21 CFR 807, Subpart E under which a device can be marketed without pre-market approval or reclassification. A determination of substantial equivalency under this notification is not intended to have any bearing whatsoever on the resolution of patent infringement suits or any other patent matters. No statements related to, or in support of substantial equivalence herein shall be construed as an admission against interest under the US Patent Laws or their application by the courts

<b>FEATURE</b>	<b>QBC STAR System</b>	<b>QBC™ AUTOREAD™ Plus</b>
Instrument Modules	Centrifuge and analyzer are in one housing.	Centrifuge and analyzer are separate modules.
Capacity	Spins and analyzes one tube at a time.	Can spin 20 tubes at once. Analyzes one tube at a time.
Centrifuge Cycle	Packing cycle is preceded by a mixing cycle where the rotor spins at 5000 RPM until the float reaches the bottom of the tube. The rotor then spins at 11,000 RPM for 4.75 minutes to separate and pack the blood into cell layers.	There is no mixing cycle. The centrifuge provided with the system spins at 12,000 RPM for 5 minutes to separate and pack the blood into cell layers.
Optical Measurement Subsystem	Optical measurement system is based on capturing the intensity profile (image) of the tube in the centrifuge rotor as it rotates past the detector assembly.	Optical measurement system is based on moving the tube linearly through a fixed optical system to build an intensity profile of the tube.
Fluorescent Measurement	Electronic scan of tube: <ul style="list-style-type: none"> <li>• Region of tube illuminated by blue flash lamp</li> <li>• Array of photodetectors</li> <li>• Electronic sequencing of array</li> </ul>	Mechanical scan of tube: <ul style="list-style-type: none"> <li>• Point on tube illuminated by blue incandescent lamp.</li> <li>• Single detector</li> <li>• Mechanical scan of tube.</li> </ul>
Cell Layer Determination	The intensity profile obtained, using 2 wavelengths of emitted light (red and green), is used to determine the beginning and the end of each cell layer.	The intensity profile obtained, using 2 wavelengths of emitted light (red and green), is used to determine the beginning and the end of each cell layer.
	The intensity profile is measured at 45-degree intervals around the tube so that any variations in the length of the cell layers may be averaged.	The intensity profile is measured at 45-degree intervals around the tube so that any variations in the length of the cell layers may be averaged.
Transmission Measurement	Electronic scan of tube: <ul style="list-style-type: none"> <li>• Region of tube illuminated by six 630nm LEDs.</li> <li>• Array of photodetectors.</li> <li>• Electronic sequencing of array</li> </ul>	Mechanical scan of tube: <ul style="list-style-type: none"> <li>• Point on tube illuminated by a single 610nm LED.</li> <li>• Single detector</li> <li>• Mechanical scan of tube.</li> </ul>
Blue Excitation Light Source	Xenon linear arc lamp with elliptical reflector illuminating a region of tube through a band pass filter with an average %T of 70% over a wavelength of 390nm to 490nm.	Tungsten filament lamp focused into a spot on the tube through a single aspherical lens and a band pass filter with an average %T of 45% over a wavelength of 410nm to 485nm.
Red Emission Filter	Plasma coated interference filter. The average %T is 80% over a wavelength of 610nm to 670nm.	A 610nm longpass red glass filter combined with infra-red glass blocking filter and blue blocking glass filter. The average %T is 10%.

FEATURE	QBC STAR System	QBC™ AUTOREAD™ Plus
Green emission filter	Plasma coated interference filter. The average %T = 70% over a wavelength of 520nm to 570nm.	A 530 green transmitting glass filter combined with glass infra-red blocking and blue blocking filters. The average %T is 20% over a wavelength of 530nm to 590nm.
Locating Bottom of Float	A transmittance scan is used to locate the float bottom, 8 red fluorescent scans, 8 green fluorescent scans are taken of the float region of the tube.	A transmittance scan is used to locate the float bottom, 8 red fluorescent scans, 8 green fluorescent scans are taken of the float region of the tube.
Identification of the Bottom of RBCs	The instrument scans the bottom of the sample assembly in fluorescence mode to pick up the fluorescent signal from the closed end stopper.	The instrument scans the bottom of the sample assembly in fluorescence mode to pick up the fluorescent signal from the closed end stopper.
Fill Volume Determination	The instrument scans the plasma area of the sample in fluorescence mode (blue light excitation). The meniscus provides a large signal transition that identifies the top of the sample column.	The instrument scans the plasma area of the sample in fluorescence mode (blue light excitation). The meniscus provides a large signal transition that identifies the top of the sample column.
Identification of buffy coat layers.	A sequence of processing the Red and Green float scans identifies the location of the three layers of buffy coat cells. This sequence uses patterns of similarities as well as dissimilarities in emission color.	A sequence of processing the Red and Green float scans identifies the location of the three layers of buffy coat cells. This sequence uses patterns of similarities as well as dissimilarities in emission color.
Verification of processed sample integrity	The data scans are evaluated to determine if the layers have formed properly, that the colors of the buffy coat have the proper signal intensity and that the patterns of these colors follow a known set of rules.	The data scans are evaluated to determine if the layers have formed properly, that the colors of the buffy coat have the proper signal intensity and that the patterns of these colors follow a known set of rules.
Algorithms	A series of numerical algorithms convert the volume of measured cell material in each layer to an equivalent cell count.	A series of numerical algorithms convert the volume of measured cell material in each layer to an equivalent cell count.
Calibration Check	Uses internal calibration targets to verify proper function of the centrifuge and optical subsystems for each test run. The results from each run are compared with results stored at the time of manufacturing.	Uses an external calibration rod that the operator must run on a daily basis. The results are compared against acceptance ranges by the user to verify proper system operation.

The modifications included in the QBC STAR system were assessed through risk analysis and verification tests were performed as a result of this risk analysis. The impact to the system of modifications to the sample collection tube was tested through simulated testing. The ability of the system software to appropriately reject or accept the processed samples was assessed.

Comparison of scans from multiple blood and control samples were made to determine equivalence between the new optical components and those used on the previously cleared product. Validation through accuracy testing of venous and capillary samples showed equivalent performance to the previously cleared product.

Although the QBC STAR Centrifugal Hematology System has modifications from the previously cleared QBC AUTOREAD Plus System these modifications do not present new issues of safety and effectiveness.



DEPARTMENT OF HEALTH & HUMAN SERVICES

SEP 23 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Ms. Monica E. Giguere  
Regulatory Affairs Associate  
Becton Dickinson & Company  
7 Loveton Circle  
Sparks, Maryland 21152

Re: K992849  
Trade Name: Becton Dickinson & Company, QBC™ STAR Centrifugal Hematology System  
Regulatory Class: II  
Product Code: GKZ  
Dated: August 20, 1999  
Received: August 24, 1999

Dear Ms. Giguere:

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.

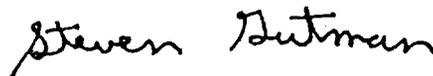
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,

A handwritten signature in black ink that reads "Steven Gutman". The signature is written in a cursive style with a large initial 'S' and 'G'.

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 (if known) K992849

Device Name: QBC STAR™ Centrifugal Hematology System

**Indications For Use:**

The QBC STAR Centrifugal Hematology System provides a diagnostic hematology profile on venous or capillary blood: hematocrit, hemoglobin, MCHC (Mean Corpuscular Hemoglobin Concentration, platelet count, white blood cell count, granulocyte count (% and number) and lymphocyte/monocyte count (% and number).

  
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(Division Sign-Off)  
Division of Clinical Laboratory Devices  
510(k) Number K992849

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

Concurrence of CDRH, Office of Device Evaluations (ODE)

*Prescription* ✓

(Optional Format 3-10-98)