

NOV 23 2004

K041882

**510(k) Summary
for
FlowCare™ System**

1. SPONSOR

PointCare Technologies, Inc.
200 Homer Avenue M100
Ashland, MA 01721

Contact Person: Dwight Kirkpatrick, Ph.D., Director of Product Development
Telephone: 508-881-7303

Date Prepared: July 8, 2004

2. DEVICE NAME

Proprietary Name: FlowCare™ System
Common/Usual Name: Automated Immune Hematology System
Classification Name: Automated Differential Cell Counter

3. PREDICATE DEVICES

- Coulter® Gen-S Hematology Analyzer
Beckman Coulter, Inc.
K962988
- Coulter® LH750 Hematology Analyzer
Beckman Coulter, Inc.
K032342 and K011342
- Coulter® tetraONE™ System for EPICS XL Flow Cytometry Systems
Beckman Coulter, Inc.
K990172

4. DEVICE DESCRIPTION

The FlowCare System is a compact benchtop immune hematology system that reports CD4 T-Lymphocyte count and percentage in conjunction with White Blood Cell (WBC) count, and total Lymphocyte count and percentage from analysis of a whole blood sample. The FlowCare System is comprised of an analysis instrument,

a touch screen computer and a standard inkjet printer. The FlowCare CD4 Reagent Kit is used in conjunction with the FlowCare System.

All assay steps are performed on whole blood with capped bar-coded reagent tubes designed for use on the FlowCare System. All assay aspiration, dispensing and mixing steps are automated. The FlowCare System reports parameter results on the basis of software analysis of light scatter measurements with the use of non-fluorescent reagents. Automated cell population cluster analysis is performed by the software and results provided with no operator interpretation.

5. INTENDED USE

The FlowCare System is an automated immune hematology system intended for *in vitro* diagnostic use in the direct enumeration of White Blood Cell populations and certain T-lymphocyte subsets from human whole blood.

Whole blood samples can be analyzed with the FlowCare System for the following parameters:

- White Blood Cell Count
- Lymphocyte Percentage (of White Blood Cells)
- Lymphocyte Number
- CD4 T-Lymphocyte Count
- CD4 Percentage (of total Lymphocytes)

The FlowCare System and its methods for immune hematology analysis are intended for *in vitro* diagnostic use in clinical laboratory settings.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The FlowCare System reports CD4 T-Lymphocyte counts and percentage in conjunction with White Blood Cell (WBC) count and total Lymphocyte count information, on the basis of software analysis of light scatter measurements with the use of non-fluorescent reagents. The FlowCare System and predicate devices are all intended for the determination of well-established parameters. All of the devices utilize anticoagulated whole blood as the initial specimen. Additionally, all of the devices employ flow-based technologies. The primary difference between the FlowCare System and the predicate devices is that the FlowCare System includes a single compact instrument whereas the predicate hematology analyzer and flow

cytometer are larger, more complex systems that must be used in conjunction with each other to provide results for the five parameters included in this 510(k) Premarket Notification.

7. PERFORMANCE TESTING

Electrical Testing

The FlowCare Instrument underwent electrical safety testing and electromagnetic compatibility testing. The instrument was found to be in compliance with applicable requirements of UL 61010A-1, CSA C22.2 1010-1, EN 61326-1 and EN 55011 (CISPR 11).

Nonclinical Testing

A precision study was performed to assess the within-run and total precision of the FlowCare System by replicate measurements of control materials for three days. On each day, testing consisted of three separate runs of three replicates each with each level of control material. In addition, another precision study was performed to assess within-day precision using whole blood samples. The samples were analyzed in three separate runs of three replicates each over the course of one day. Results of these studies demonstrated acceptable precision of the FlowCare System.

A linearity study was performed to assess the performance of the FlowCare System over a wide range of cell concentrations for the measured parameters. CD4 count was further evaluated in the low range. The results were tested for linearity and least squares regression analysis was performed. Linearity was demonstrated in all cases.

A carryover study was performed to assess the effect of a whole blood sample on background counts in subsequent analyses for the measured parameters. Negligible carryover was observed.

Clinical Testing

A multi-site prospective study was conducted at four investigational sites to evaluate the performance of the FlowCare System with other commercially available methods. A total of 414 evaluable samples were analyzed across all participating sites. Data analyses were performed for comparison of the FlowCare method to the reference methods, and for the determination of an expected normal values reference range for the FlowCare method. The analyses of the pooled data showed comparable means and ranges for the FlowCare and reference method parameters.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

PointCare Technologies, Inc.
c/o Ms. Cynthia A. Sinclair, RAC
Senior Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

NOV 23 2004

Re: k041882
Trade/Device Name: PointCare Technologies, Inc., FlowCare™ System
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: II
Product Code: GKZ
Dated: October 18, 2004
Received: October 20, 2004

Dear Ms. Sinclair:

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.

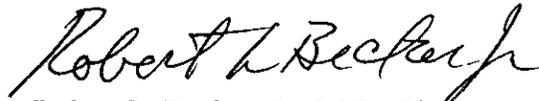
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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.

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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). You may obtain other general information on your responsibilities under the Act 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,

A handwritten signature in black ink that reads "Robert L. Becker, Jr." in a cursive script.

Robert L. Becker, Jr., M.D., Ph.D.

Director

Division of Immunology and Hematology Devices

Office of In Vitro Diagnostic Device Evaluation and Safety

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K041882

Device Name: FlowCare™ System

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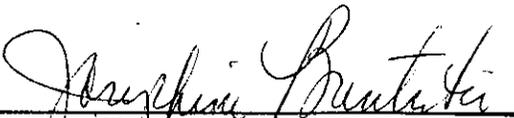
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-the-Counter Use _____
(21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)


Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K041882