K072869

510(k) Summary
for
PointCare *NOW* System

1. SPONSOR

JAN 14 2008

PointCare Technologies, Inc.
181 Cedar Hill Street
Marlborough, MA 01752

Contact Person: Maurice N. Doire, Dir. of Quality Assurance and Regulatory Affairs

Telephone: 508-281-6925 ext. 22

Date Prepared: October 3, 2007

2. DEVICE NAME

Proprietary Name:	PointCare *NOW* System
Common/Usual Name:	Automated Immune Hematology System
Classification Name:	Automated Differential Cell Counter

3. PREDICATE DEVICES

- FlowCare/AuRICA Flow Cytometer
  PointCare Technologies, Inc.
  K041882
- Excell 22 Hematology Analyzer
  MWI, Inc.
  K991539
- Sysmex XE-2100 Hematology Analyzer
  Sysmex Corp.
  K992875
- FlowCare PLG™ System for EPICS XL Flow Cytometry Systems
  Beckman Coulter, Inc.
  K043215

4. DEVICE DESCRIPTION

The PointCare *NOW* System is a compact bench top immune hematology system that from analysis of a whole blood sample reports the hematology parameters identified within the Intended Use section below. The PointCare *NOW* System consists of an analysis instrument with an integrated touch screen interface and a commercially available tape roll printer.

The CD4*NOW* Gold Pack is used within the PointCare *NOW* System and all assay steps are performed on whole blood with capped bar-coded reagents designed for use on the PointCare NOW System. All assay aspiration, dispensing and mixing steps are automated. The PointCare NOW 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 PointCare *NOW* System is an automated hematology system intended for *in vitro* diagnostic use in performing the direct enumeration of major white blood cell populations, certain T-lymphocyte subsets, and hemoglobin concentration from human whole blood.

Whole blood samples can be analyzed with the PointCare *NOW* System for the following parameters:

- White Blood Cell Count (Changed principle from FlowCare)
- Lymphocyte Count (Unchanged from FlowCare)
- Lymphocyte Percentage (of White Blood Cells) (Unchanged from FlowCare)
- CD4 T-Lymphocyte Count (Unchanged from FlowCare)
- CD4 Percentage (of total Lymphocytes) (Unchanged from FlowCare)
- Monocyte Count (New parameter not on FlowCare)
- Monocyte Percentage (of White Blood Cells) (New parameter not on FlowCare)
- Neutrophil Count (New parameter not on FlowCare)
- Neutrophil Percentage (of White Blood Cells) (New parameter not on FlowCare)
- Eosinophil Count (New parameter not on FlowCare)
- Eosinophil Percentage (of White Blood Cells) (New parameter not on FlowCare)
- Hemoglobin Concentration (New parameter not on FlowCare)

The PointCare *NOW* 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 system reports it's parameters on the basis of software analysis of light scatter measurements with the use of non-fluorescent reagents. The PointCare NOW 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 PointCare NOW System is a single compact instrument whereas the predicate hematology analyzers and flow cytometers are larger, more complex systems that must be used in conjunction with each other to provide results for the twelve parameters included in this 510(k) Premarket Notification.

7. PERFORMANCE TESTING

Electrical Testing

The PointCare NOW Instrument underwent electrical safety testing and electromagnetic compatibility testing. The instrument was found to be in compliance with applicable requirements of CFR 47 Part 15 Class A, IEC 61000, UL 61010, and EN 61326.

Nonclinical Testing

A precision study was performed to assess the within-run and total precision of the PointCare NOW 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 ten replicates each over the course of one day. Results of these studies demonstrated acceptable precision of the PointCare NOW System.

A linearity study was performed to assess the performance of the PointCare NOW System over a wide range of cell concentrations for the measured parameters. WBC count and Hemoglobin were 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 PointCare NOW System with other commercially available methods. A total of 249 evaluable samples were analyzed across all participating sites. Data analyses were performed for comparison of the PointCare NOW method to the reference methods. The analyses of the pooled data showed comparable means and ranges for the PointCare NOW and reference method parameters.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 14 2008

PointCare Technologies, Inc.
C/O Maurice N. Doire
181 Cedar Hill Street
Marlborough, Massachusetts 01752

Re: k072869
Trade/Device Name: PointCare Now System
Regulation Number: 21 CFR 864.5220
Regulation Name: Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: October 4, 2007
Received: October 9, 2007

Dear Mr. Doire:

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.

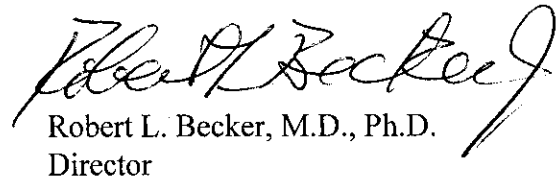
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish 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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Robert L. Becker, M.D., Ph.D.
Director
Division of Immunology and Hematology
Office of *In Vitro* Diagnostic Device Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K072869

Device Name: PointCare *NOW* System

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- Neutrophil Count
- Neutrophil Percentage (of White Blood Cells)
- Eosinophil Count
- Eosinophil Percentage (of White Blood Cells)
- Hemoglobin Concentration

The PointCare *NOW* System and its methods for analysis are intended for *in vitro* diagnostic use in clinical laboratory settings.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (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) K072869