K111534

AUG 2 2012

## 510(k) Summary

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|---|---|
| **Submitter:** | Diatron US Inc.<br>14026 W. 107th Street<br>Lenexa, Kansas 66215-2005 |
| **Contact Person:** | Michael Switzer, Director, Quality Assurance<br>P: 954-790-9550<br>F: 954-827-2644<br>E: mike.switzer@diatron.com |
| **Date Prepared:** | April 27, 2012 |
| **Trade Name:** | Abacus 3CP, Automated Hematology Analyzer |
| **Classification:** | Class II<br>Automated Differential Cell Counter<br>21 CFR §864.5220 |
| **Product Code:** | GKZ |
| **Predicate Device(s):** | The subject device is equivalent to the following device:<br>Abbott CELL-DYN® 1800 (K030513) |
| **Device Description:** | The 'Abacus 3CP' is a fully automated, bench top hematology cell counter with a cap piercing function. It uses the impedance-method for counting cells passing through a small aperture, and measures the hemoglobin content of red blood cells using a photometric method. The analyzer features a color graphical LCD display module and a foil keypad of 29 keys including 6 software buttons, 6 function keys and a START button. The instrument allows printing reports to an external printer (USB port), or can have an optional built-in printer module. Its internal memory is capable of storing 1000 records with full histograms, and individual patient data. The QC measurements are stored in a separate database. The software operating the instrument can be updated by using a USB flash memory device. The instrument can be connected to a host computer for uploading records in its memory through a USB SLAVE port (USB B) or serial link (RS232). Archiving records to an USB flash memory device is also possible. |
| **Indications for Use:** | The Diatron Abacus 3CP System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM#, MID%, MID#, GRA%, GRA#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV in $K_3$EDTA anti-coagulated venous whole blood samples. The Diatron Abacus 3CP is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges. |
| **Functional and Safety Testing:** | To verify that device design met it's functional and performance requirements, a representative sample of the device underwent software and system verification and validation testing, in accordance with Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood cells. A risk and hazard analysis was performed per ISO 14971. |

**Substantial Equivalence:**

| Similarities | | |
|---|---|---|
| **Item** | **Diatron Abacus 3CP** | **Abbott CELL-DYN 1800** |
| Indication for Use | The Diatron Abacus 3CP System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM#, MID%, MID#, GRA%, GRA#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV in $K_3$EDTA anti-coagulated venous whole blood samples. The Diatron Abacus 3CP is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges. | The CELL-DYN 1800 System is an automated, multiparameter hematology analyzer designed to report sixteen parameters relating to the cells of EDTA-anticoagulated blood. |
| Number of Parameters | 16 | Same |
| Methodology | WBC = Impedance<br>LYM = Calculated<br>LYM% = Derived<br>MID = Calculated<br>MID% = Derived<br>GRA = Calculated<br>GRA% = Derived<br>RBC = Impedance<br>HGB = Photometric<br>HCT = Calculated<br>MCV = Derived<br>MCH = Calculated<br>MCHC = Calculated<br>RDW = Derived<br>PLT = Impedance<br>MPV = Derived | Same |
| Sample Type | $K_3$ EDTA anticoagulated venous whole blood | Same |
| Sample Container | Open and Closed | Same |
| Sampling System | Manual | Same |
| Samples per hour | 60 | Same |
| Aperture Diameter | WBC 100 µm; RBC/PLT 80 µm | Same |

| Differences | | |
|---|---|---|
| **Item** | **Diatron Abacus 3CP** | **Abbott CELL-DYN 1800** |
| Sample Volume | Open Vial Mode – 100 µL<br>Closed Vial Mode – 100 µL | Open Vial Mode – 30 µL<br>Closed Vial Mode – 450 µL |
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**Performance:**

All required software and system verification and validation procedures have been executed and analyzed per FDA recommended standards and the Class II Special Controls Guidance Document: Premarket Notifications for Automated Differential Cell Counters for Immature or Abnormal Blood Cells. All risk and hazard analysis have been performed and documented per ISO 14971 guidelines. All performance and accuracy data and data analysis in this submission support and substantiate equivalence to the selected predicate device (Abbott CELL-DYN® 1800 (K030513)).

**Conclusion:**

Diatron considers the Abacus 3CP to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

10903 New Hampshire Avenue
Silver Spring, MD 20993

AUG 02 2012

Diatron US Inc.
c/o Mr. Michael Switzer
Director, Quality Assurance
14026 W. 107th Street
Lenexa, KS 66215-2005

Re: k111534
Trade/Device Name: Abacus 3CP
Regulation Number: 21 CFR § 864.5220
Regulation Name: Automated differential cell counter
Regulatory Class: Class II
Product Code: GKZ
Dated: July 30, 2012
Received: July 31, 2012

Dear Mr. Switzer:

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 class II (Special Controls), 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); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); 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 Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

For Leena Philip

Maria M. Chan, 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 Form

510(k) Number (if known): k111534

Device Name: Abacus 3 CP

Indications for Use:

The Diatron Abacus 3CP System is a quantitative multi-parameter automated hematology analyzer designed for in-vitro-diagnostic use in clinical laboratories for enumeration of the following parameters: WBC, LYM%, LYM#, MID%, MID#, GRA%, GRA#, RBC, HGB, HCT, MCV, MCH, MCHC, RDW, PLT, MPV in $K_3$EDTA anti-coagulated venous whole blood samples. The Diatron Abacus 3CP is indicated for use to identify patients with hematologic parameters within and outside of established reference ranges.

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

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

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Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

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