510(k) Summary
for
D3 Hematology Analyzer

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92

The assigned 510(k) number is : K071562

1. APPLICANT

DREW Scientific, Inc.
4230 Shilling Way
DALLAS, Texas 75237

DEC 1 1 2007

Contact Person: Roger BOURREE

Telephone: 214-210-4900

Fax: 214-210-4950

Date Prepared: 2nd June 2007

2. DEVICE NAME

Proprietary Name:	**D3 Hematology Analyzer**
Common/Usual Name:	Automated differential cell counter
Classification Name:	Automated differential cell counter (21 CFR §864.5220)
Device Class	Class II : Special Controls Guidance Document
Product Code:	GKZ , Counter, Differential Cell

3. PREDICATE DEVICE

DREW Scientific, Inc. DataCell 18MS (K945678)

4. DEVICE DESCRIPTION

The **D3 Hematology Analyzer** is a stand-alone benchtop, clinical laboratory instrument which analyzes in-vitro samples of whole blood to provide complete blood count and leucocyte differential count using the impedance & spectrophotometry techniques.

5. INTENDED USE

The **D3 Hematology Analyzer** is a fully automated (microprocessor controlled) quantitative hematology analyzer used for the in vitro diagnostic testing of whole blood specimens.

6. TECHNOLOGICAL CHARACTERISTICS & SUBSTANTIAL EQUIVALENCE

The **D3 Hematology Analyzer** can be considered substantially equivalent to the already cleared device **DATACELL 18MS** (K945678) with respect to the indications for use, the hematological parameters for complete blood count and differential leukocyte count, and the principles of operation (fundamental scientific technology).

The data and information supplied in this submission demonstrates substantial equivalence to their respective predicate devices :

	Predicate device (K945678)	**New Device**
Device Name	**DATACELL 18MS Hematology Analyzer**	**D3 Hematology Analyzer**
Manufacturer	Drew Scientific, Inc (Previously: DANAM Electronics)	Drew Scientific, Inc.
Instrument	Hematology Analyzer, CBC + 3 part differential	Identical
Analyzer description	Analyzer with built-in computer	Stand-alone touch screen analyzer
Measurement Principle:		
WBC	Impedance	Identical
RBC	Impedance	Identical
Hgb	Spectrophotometer	Identical
MCV	Derived from RBC cell size distribution	Volume integration

	Predicate device (K945678)	New Device
Device Name	**DATACELL 18MS Hematology Analyzer**	**D3 Hematology Analyzer**
HCT	Calculation	Volume integration
Plt	Impedance	Identical
RBC Wavelength	540nm	555nm
Mode	Open Tube	Identical
Parameters:		
	16 parameters	16/ 18 parameters
Leukocyte	WBC Total White Blood Cells count LYM% Lymphocytes in percentage LYM# Lymphocytes total count MID% MID cells in percentage MID# MID Cell total count GRA% Granulocytes in percentage GRA# Granulocytes total count	Identical
Erythrocyte	RBC Red Blood Cells count Hgb Hemoglobin Hct Hematocrit MCV Mean Corp. Volume MCH Mean Corpuscular Hemoglobin MCHC Mean Corpuscular Hemoglobin Concentration RDW : Red Blood cells Distribution Width	Identical
Thrombocyte	PLT Platelet count MPV Mean Platelet Volume	Identical PDW* Platelet Distribution Width PCT* Thrombocrit *For investigation use only in the United States of America.
Throughput	60 samples/hour	Identical
Sample Type	Whole blood	Identical

	Predicate device (K945678)	New Device
Device Name	**DATACELL 18MS Hematology Analyzer**	**D3 Hematology Analyzer**
Specimen sample volume	135.0 µl (whole blood), 65.0 µl (whole blood in samples saver mode) 25µl of whole blood diluted into 6.0ml of diluent for prediluted sample mode	10.0 µl (whole blood), 25.0 µl of whole blood diluted into 0.5 ml of diluent for prediluted sample mode
Anti-coagulant	EDTA K2 / K3	Identical
Identification patient samples	Manual entry (alphanumeric), Bar codes reader (optional)	Identical
Display	LCD Computer screen	Integrated Touch Screen
Computer	External computer	Integrated stand-alone
Reagents (analysis & cleaning)	Individually packaged reagents : DREW EX-ISO (Diluent, 20L) DREW, EX-LYSE (500 ml) DREW, EZ-CLEAN (Cleaner, 5L or 10L)	Identical reagents, packaged differently : D3 Pac, consisting of : - DREW, EX-ISO (Diluent, 4L) - DREW, EX-Lyse (120ml) - DREW EZ-CLEAN (Cleaner, 500 ml)
Quality Controls	EX-TROL	Identical
Calibrators	EX-CAL	Identical

7. PERFORMANCE TESTING

The non-clinical studies and data analysis were carried out in accordance with appropriate indications given by the FDA guidelines.

Accuracy, Repeatability, Linearity, Carryover , Sample Stability studies demonstrated acceptable performance per the manufacturers specifications.

The device meets with the UL 61010-1 standard of the International Electro-technical Commission on electrical equipment for measurement, control, and laboratory use. Further more, is compliant with the IEC 60601-1-2 standard for Electromagnetic Compatibility.

8. CONCLUSIONS FOR PERFORMANCE TESTING

The Performance Testing conclude that the safety and effectiveness of the device is not compromised, meeting all acceptance criteria and demonstrating that the devices are substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 1 2007

Drew Scientific, Inc
C/O Roger Bourree
4230 Shilling Way,
Dallas, Texas 75237

Re: K071562
Trade/Device Name: D3 Hematology Analyzer, Model D3
Regulation Number: 21 CFR 864.5220
Regulation Name: Automated Differential Cell Counter
Regulatory Class: Class II
Product Code: GKZ
Dated: June 7, 2007
Received: June 7, 2007

Dear Mr. Bourree:

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 the Code of Federal Regulations, Title 21, Parts 800 to 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0377. 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,

for Robert L. Becker, Jr., MD, PhD.
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): K071562

Device Name: DREW D3 Hematology Analyzer

Indications For Use:

The **DREW D3 Hematology Analyzer** is a fully automated (microprocessor controlled) quantitative hematology analyzer used for the *in vitro* diagnostic testing of whole blood specimens.

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

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

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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

(k) K071562