

JUL - 1 1999

## 510(k) Summary

MWI, Inc.

Common/Classification Name: Counter, Differential Cell Hematology Analyzer

Sponsor: MWI, Inc.  
d.b.a. Danam Electronics  
4230 Shilling Way  
Dallas, TX 75237  
Tel (214) 210-4900  
Fax (214) 210-4949

Contact: Greg Witherspoon

Prepared: April 29, 1999

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 K991539.

### A LEGALLY MARKETED PREDICATE DEVICES

To show that **EXCELL 22** is safe and effective, it is compared to two legally marketed devices. The Cell-Dyn 3000 WBC differential is well respected in the industry as being fundamentally sound in theory and implementation, but because of well known WBC fragile lymphocyte counting problems it is not used for the WBC count for this comparison. The design of the **EXCELL 22** is derived from the proven Danam DATACELL 18MS that traces its performance equivalence to the Coulter S+IV. For this reason, the basic hematology parameters are compared to the Coulter S+IV and the white cell differential is compared to the Cell-Dyn 3000. The laser optical WBC differential that was added to the DATACELL 18MS is similar to that of the Cell-Dyn 3000.

The Coulter S+IV reproducibility and linearity is superior to the Cell-Dyn products and makes a better comparison for those parameters which are provided.

The predicate devices are marketed under 510(k) clearance. The Cell-Dyn 3000 is manufactured by Sequoia Turner Corporation, (now Abbott Laboratories) under K890491. The DATACELL 18MS is manufactured by MWI, Inc. d.b.a. Danam Electronics under K945678.

## **B DEVICE DESCRIPTION**

The **EXCELL 22** is a DATACELL 18MS with an additional optical channel for performing a five-part white cell differential. The five-part optical white cell differential system is substantially equivalent to the Cell-Dyn 3000.

Modifications to the DATACELL 18MS present in the new instrument are:

- Addition of a laser excited multi dimensional flow cytometer
- addition of a reagent for the optical flow cell
- provision for collecting data from the optical detectors
- replacing of AC motors with DC motors to make the product suitable for international applications
- replacing the internal PC computer and monitor with an external PC to gain room for the optical detection system
- provision in the slide valve for the additional dilution for the WBC optical measurement
- addition of hydrodynamic focus sample injection system for the WBC
- improved dilution logic to speed up the measurement
- improved platelet aperture system called the von Behrens silencer.

The operating modes are the same as the DATACELL 18MS.

## **C INTENDED USE**

The subject product, **EXCELL 22**, is an in vitro diagnostic instrument for use in counting blood cells, classifying white blood cells (WBC), and flagging specimens containing abnormal blood cells. The marketed instruments, DATACELL 18MS and Cell-Dyn 3000, have the same intended use.

## **D TECHNOLOGICAL CHARACTERISTICS**

The subject product, **EXCELL 22**, has similar technological characteristics as the predicate devices. The **EXCELL 22** is simply the addition of an optical five-part white cell differential to the Danam DATACELL 18MS. The white cell differential is closely related to the technology utilized by the Cell-Dyn 3000. The other changes are refinements of the technology used in the DATACELL 18MS.

## E TESTING

Evaluation of performance characteristics was done in the Danam QC laboratory where the reference instruments are routinely maintained for monitoring performance of Danam reagents and controls. The instruments are controlled using Coulter 4C for the S+IV and Streck Laboratories Para 12 plus for the Cell-Dyn 3000. Slight calibration offsets exist for the different brands of calibrator and control products. Specimens for the evaluation were obtained from various sources including physicians' offices, oncology clinics, and hospital laboratories.

### Linearity

Linearity is set on all Danam Excell products by a serial dilution technique plotting all counted parameters against hemoglobin. The hemoglobin is assayed for each dilution to verify hemoglobin linearity. This is a particularly useful technique since the hemoglobin determination is based on different technology from the cell counts.

The results of the linearity test indicate that the **EXCELL 22** meets the performance specifications contained in the Operator's Reference Manual.

### Precision

Studies of instrument precision are used to confirm the reproducibility of the initial blood sampling operation. Precision is evaluated by replicate analyses of control material. The precision studies consist of 10 consecutive replicates of high, normal, and low control material. The results of the precision test indicate that the **EXCELL 22** meets the performance specifications contained in the Operator's Reference Manual.

To evaluate precision of day to day operations, statistics are derived from the daily testing of control material when the testing of patient samples was done. All values measured are within acceptable ranges and their coefficients of variation are less than the specified  $\pm 2SD$  limits published for the control product when it is used with the Cell-Dyn 3000. All control runs are within the expected range and indicate satisfactory performance of the **EXCELL 22**.

## Accuracy

Accuracy is evaluated by comparison of measured and calculated parameters from testing of clinical specimens by **EXCELL 22** and the reference instruments. The WBC differential percentages and flags were referenced to the Cell-Dyn 3000. All other parameters were compared with the Coulter S+IV. Because no established standards are available for hematology analyzers, instruments were calibrated to a commercially available calibrator stated to be calibrated according to NCCLS protocols for some parameters.

Comparison of results is made between samples counted by the **EXCELL 22** and the reference instruments. Two studies were performed. The first study is of a large number of samples comparing the **EXCELL 22** and the reference instruments to determine correlation or accuracy of the subject instrument. The second study involved the addition of reference method differential determination to resolve flag differences between the Cell-Dyn 3000 and the **EXCELL 22**.

### Study 1

This study consisted of 390 whole blood samples obtained from various sources, collected as defined in NCCLS H3-A2, intended to be representative of the universe that the **EXCELL 22** is intended to serve. The specimens were tested during the period from February 08, 1999 to April 08, 1999.

Patient samples that gave a white blood cell differential morphological positive result on the Cell-Dyn 3000 reference instrument and the **EXCELL 22** were eliminated from the white blood cell differential count portion of the correlation study, as recommended in NCCLS H20-A, resulting in a reduction of the samples for the WBC differential count portion to 268.

Patient samples giving a PLT/RBC morphological positive result on the reference instrument and instrument under evaluation were eliminated from the PLT, RBC, MCV, RDW, HGB portion of the correlation study, as recommended in NCCLS H20-A, resulting in a reduction of the samples to 326.

All samples were promptly analyzed on the **EXCELL 22**, Coulter S+IV, Cell-Dyn 3000 and the results recorded.

The correlation coefficient, slope and y-Intercept were determined for each parameter. Measured parameter results (WBC, RBC, Hgb, MCV, Plt) obtained by the **EXCELL 22** exhibited coefficients of correlation is greater than 0.980.

Calculated RDW and WBC differential parameter results are considered to be accurate when the slope of the line of correlation is within the range of 0.95 to 1.05 and the coefficient of correlation is greater than 0.900 for all cell types except the basophils. The basophil is an infrequently occurring cell type that is reduced in correlation coefficient due to the very small frequency range and the statistical noise caused by the low number of basophils observed.

The results of this study indicate that the **EXCELL 22** is accurate and is substantially equivalent to the legally marketed reference instruments.

#### Study 2

The purpose of this study is to evaluate the flagging characteristics of the **EXCELL 22**. This study consisted of 173 whole blood samples obtained from various sources, collected as defined in NCCLS H3-A2, and intended to be representative of the universe that the **EXCELL 22** is intended to serve. The specimens were tested during the period from March 10, 1999 to April 08, 1999.

All samples were promptly analyzed by the **EXCELL 22**, Cell-Dyn 3000 and the results recorded. A slide was made of each specimen for further analysis.

The **EXCELL 22** and the Cell-Dyn 3000, both report a DIFF flag when they cannot reliably discriminate the cell clusters and produce a meaningful five part white cell differential. This is typically due to the presence of highly abnormal cell distributions, abnormal cell morphology, or deterioration of sample condition.

On all samples reported with a DIFF flag by the Cell-Dyn 3000 and/or by the **EXCELL 22**, three different technologists performed a manual differential count. The manual count from each technologist was recorded, and the average result of all three was used in order to minimize the effects of human error and to improve statistical confidence of the observation.

The **EXCELL 22** reported no false negative and 1 false positive result; the Cell-Dyn 3000 reported no false negative and 7 false positive results.

The result of the **EXCELL 22** flagging study indicated that no unreliable WBC differential results were reported.

## **F CONCLUSIONS**

Careful analysis of the results of comparison of the **EXCELL 22** with the reference instruments clearly establish the substantial equivalence of the **EXCELL 22** with the legally marketed devices. The **EXCELL 22** is safe and effective for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

JUL - 1 1999

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Gregory A. Witherspoon  
Manager, Quality Affairs and Regulatory Affairs  
MWI, Inc.  
dba DANAM Electronics  
4230 Shilling Way  
Dallas, Texas 75237

Re: K991539  
Trade Name: EXCELL™ 22  
Regulatory Class: II  
Product Code: GKZ  
Dated: April 30, 1999  
Received: May 3, 1999

Dear Mr. Witherspoon:

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 (Premarket 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.

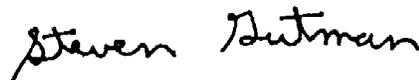
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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,



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



**MWI, INC.**

dba **DANAM** ELECTRONICS

4230 SHILLING WAY  
DALLAS, TEXAS 75237  
(214) 210-4900  
(800) 433-0945  
FAX (214) 210-4949

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510(k) Number (if known): K991539

Device Name: EXCELL™ 22

**Indication for Use:** The EXCELL™ 22 is an in-vitro diagnostic instrument for use in counting blood cells, classifying white blood cells (WBC) and flagging specimens containing abnormal blood cells in clinical laboratories at diverse sites. Per NCCLS H20A section 4(9), flagging is defined as "identifying a sample or blood film for further attention or review".

**The EXCELL 22 reports on the following parameters:**

|      |   |
|------|---|
| WBC  | White Blood Cells (Leukocytes)                          |
| RBC  | Red Blood Cells (Erythrocytes)                          |
| Hgb  | Hemoglobin Concentration                                |
| Hct  | Hematocrit (relative volume of erythrocytes)            |
| MCV  | Mean Corpuscular (erythrocyte) Volume                   |
| MCH  | Mean Corpuscular (erythrocyte) Hemoglobin               |
| MCHC | Mean Corpuscular (erythrocyte) Hemoglobin Concentration |
| RDW  | Red Blood Cell (erythrocyte volume) Distribution Width  |
| Plt  | Platelet or Thrombocyte Count                           |
| MPV  | Mean Platelet (thrombocyte) Volume                      |

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Concurrence of CDRH, Office of Device Evaluation (ODE)



**MWI, INC.**

dba **DANAM** ELECTRONICS

4230 SHILLING WAY  
DALLAS, TEXAS 75237  
(214) 210-4900  
(800) 433-0945  
FAX (214) 210-4949

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510(k) Number (if known): K991539

Device Name: EXCELL™ 22

Parameters Continued:

|      |                             |
|------|-----------------------------|
| LY#  | Lymphocyte (number)         |
| LY%  | Lymphocyte (percent of WBC) |
| MO#  | Monocyte (number)           |
| MO%  | Monocyte (percent of WBC)   |
| BA # | Basophil (number)           |
| BA%  | Basophil (percent of WBC)   |
| NE#  | Neutrophil (number)         |
| NE%  | Neutrophil (percent of WBC) |
| EO#  | Eosinophil (number)         |
| EO%  | Eosinophil (percent of WBC) |

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)  
Division of Clinical Laboratory Devices K991539  
510(k) Number

Description ✓