NOV - 7 1997

K973050

510(k) Summary

Designated Point of Contact: Otto Stellner
Title: Vice President, Regulatory Compliance
Project Manager: Alyn J. Hansen
Date: August 5, 1997

Trade Name: *MICRO21* with WBC Estimate
Classification Name: Automated Cell Locating Device
Classification Number: 81JOY
Class: II
Regulation Number: 864.5260

Description

The *MICRO21* with WBC Estimate is a new intended use that follows the same process as the currently approved *MICRO21* with White Blood Cell (WBC) Differential (Diff). The *MICRO21* with WBC Diff, Ref. No. K925670/A, is an automated microscopic system that locates WBCs, stores digital images of the cells and displays the images in an organized manner to aid technologists in performing the WBC Diff procedure. The *MICRO21* process is substantially equivalent to the manual microscopic process.

The *MICRO21* with WBC Estimate is an automated microscopic procedure that calculates an estimate of WBCs/μL using the information collected during the *MICRO21* with WBC Differential. Upon completion of the review process by a technologist, an algorithm calculates the WBC Estimate by using the number of classified WBCs and the number for low-power (200x magnification) fields visited. An estimated range for the WBCs/μL is calculated and reported. A summary of the *MICRO21* with WBC Estimate process is as follows:

1. Patient blood smears are made on glass slides using an automated blood smearing device.
2. Each slide is stained with Wright's stain.
3. The slides are barcoded, placed into a slide frame and inserted into the *MICRO21* for processing.
4. The *MICRO21* locates WBCs and stores digital images of the cells.
5. The technologist reviews the stored images on a color monitor and verifies the white cell classification.
6. The *MICRO21* automatically calculates the WBC Estimate by dividing the classified WBCs by the number of low-power fields visited.
7. At the completion of the procedure, the WBC Estimate is displayed as a range and is available on the Final Report display and printout.

Test Method 1, Accuracy

To confirm equivalence, 86 blood smear samples with Total WBC Counts ranging from 100 to 36,100 cells/μL were used. The study correlated the WBC Estimate on the *MICRO21* with the total White Blood Cell Count generated by an automated cell counter such as the TOA Sysmex NE 9000, Coulter STKS or Technicon H2 and compared the *MICRO21* with WBC Estimate to the Manual WBC Estimate. The automated cell counters were controlled and calibrated according to manufacturer's specifications at the various sites.

4360 Northlake Blvd., Suite 214 • Palm Beach Gardens, FL 33410
Phone (561) 627-0344 • FAX (561) 627-0344

Test Method 2, Precision

To confirm the *MICRO21* intra-instrument precision, one blood smear was prepared from each of 10 specimens. Each blood smear was processed 10 times in random order. The stored images were then presented to a technologist for review. The results were used to provide intra-instrument and within specimen precision.

Test Method 3, Correlation, WBC Classification Review

The technologist reviewed the images of nucleated cells captured by the *MICRO21* and verified the image classification. The number of confirmed white blood cells (real cells) after the review was completed was the number used in the *MICRO21* calculation of WBC Estimate. Non-white blood cells were reclassified as smudges, ignore or nucleated red blood cells. Three technologists performed the *MICRO21* reviews.

Calculation of the *MICRO21* with WBC Estimate

The method is based on the number of WBCs located within an area of optimal cell distribution and is correlated with the absolute WBC/μL of blood. The calculation of the *MICRO21* with WBC Estimate is based on the following formulation:

$$\frac{\text{Real Cells}}{\text{Fields}} \times \text{CF} = \textit{MICRO21}\ \text{WBC Estimate}$$

- Real Cells = the number of confirmed WBCs
- Fields = the number of low-power (200x magnification) fields visited to capture the Real Cells
- CF = Correction Factor, the numerical factor need to match *MICRO21* WBC Estimate with Total WBC Count obtained using automated blood cell analyzer.
- *MICRO21*WBC Estimate = WBC/μL of blood

The Correction Factor was defined as the mean value of the 86 specimens tested.

Reporting the *MICRO21* with WBC Estimate

The calculated *MICRO21* WBC Estimate is displayed on the Report Screen and printed out in the Final Report. The reportable range is from 100 to ≥ 25,000 WBCs/μL and is displayed as follows:

MICRO21 WBC Estimate x,xxx - y,yyy WBC/μL

Manual WBC Estimate

The Manual WBC Estimate was obtained by reviewing 86 blood smears under 500 or 1,000x magnification and calculating an estimate based on white blood cells per 10 fields of view. Three technologists performed the manual reviews.

Conclusion

Results are reported in the Summary of Results section and confirm that the *MICRO21* with WBC Estimate is substantially equivalent to a Manual WBC Estimate. The results of this comparison confirm the safety and effectiveness of the *MICRO21* WBC Estimate for the intended use as a laboratory instrument for locating, digitally storing and displaying white blood cells to aid the technologist in performing the WBC Estimate. Examination and determination of the results must be performed by qualified individuals.

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DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. R. Otto Stellner
Vice President, Regulatory Compliance
Intelligent Medical Imaging
4360 Northlake Boulevard, Suite 214
Palm Beach Gardens, Florida 33410

NOV - 7 1997

Re: K973050
Trade Name: *MIRCO21™* with WBC Estimate
Regulatory Class: II
Product Code: JOY
Dated: August 5, 1997
Received: August 15, 1997

Dear Mr. Stellner:

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 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 requirement, 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.

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 at (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html"

Sincerely yours,

Steven Gutman

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

K913050

510(k) Number :

Device Name:
MICRO21™ with WBC Estimate

Indications for Use:

For In Vitro Diagnostic Use

Intelligent Medical Imaging, Inc.'s *MICRO21* with WBC Estimate is a laboratory instrument for locating, digitally storing and displaying white blood cells to aid the technologist in performing the WBC Estimate. Examination and determination of the results must be performed by qualified individuals.

INTELLIGENT MEDICAL IMAGING, INC. DOES NOT PROMOTE THE USE OF, PROVIDE SUPPORT FOR, MAKE CLAIMS OF EFFECTIVENESS OF OR ASSUME LIABILITY FOR THIS DEVICE IN ANY OTHER COMMERCIAL, EXPERIMENTAL OR INVESTIGATIONAL APPLICATION.

Use of this device in any manner that is inconsistent with its intended use may be in violation of federal law.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Peter E. Maxim

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

Prescription Use ✓ OR Over-The-Counter Use _____
(per 21 CFR 801.109) (Optional Format 1-2-96)

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