

K971470



SEP 16 1997

Intelligent Medical Imaging, Inc.

### 510(k) Summary

Prepared by: Ronald Lee Bartley, B.S., MT, NCA (CLS/C)  
 Title: Sr. Product Development Manager  
 Date: April 18, 1997

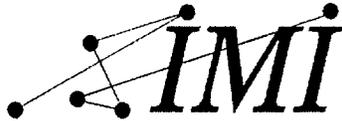
Trade Name:  
 Classification Name: Automated Cell Locating Device  
 Classification Number: 81JOY  
 Class: II  
 Regulation Number: 864.5260

### Description:

The *MICRO21*<sup>TM</sup> with Cerebrospinal Fluid is a new procedure for the *MICRO21* with the following in vitro diagnostic intended use: Intelligent Medical Imaging, Inc.'s *MICRO21*<sup>TM</sup> with Cerebrospinal Fluid (CSF) is a laboratory instrument used to perform cytological analysis by locating, digitally storing and displaying nucleated cells in human cerebrospinal fluid preparations. Examination of cellular morphology and classification must be performed by qualified individuals.

A summary of the *MICRO21* with Cerebrospinal Fluid process is as follows:

1. Patient CSF samples are prepared using the cytocentrifugation method for specimen concentration using the Cytospin® centrifuge.
2. Each slide has a black mask over the non-frosted portion with a hole in the mask for specimen placement.
3. The slide is stained using Wright's stain.
4. The slides are barcoded and placed into a frame holder, and the frame is placed on the *MICRO21* for processing.
5. The *MICRO21* locates nucleated cells.
6. The nucleated cell images are stored by the instrument and displayed on a color monitor for review by a technologist.
7. The technologist reviews the images and confirms each cell type.
8. A report of the CSF result for each patient is printed.



Intelligent Medical Imaging, Inc.

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### **Test Method 1: Method Verification and Sensitivity**

Ten slides were processed using a quality control protocol to determine the detection sensitivity of the instrument. The ability of the instrument to locate cells at low and high power was determined by manually confirming the location of real cells or the location of non-cells such as stain precipitate.

### **Test Method 2: Precision**

To confirm the *MICRO21* intra-instrument precision, three CSF specimen slides were processed eight times, each in random order. Using blinded experimental methods, the resulting images were presented to a technologist for review. The results were correlated to provide intra-instrument within slide precision.

### **Test Method 3: Correlation Study Performance**

Cerebrospinal Cell Differentials (CCDs) obtained from images located and displayed by the *MICRO21* were correlated with CCDs performed manually by qualified technologists. Fifty CSF specimens obtained from various geographic sites were used for the study.

For the manual method, two technologists processed and examined each slide by bright-field microscopy. Depending on the cellularity of the specimen, a cumulative differential of up to 250 nucleated cells were counted and classified. Any non-nucleated cells or micro-organisms were recorded if present. In addition, any cell clustering or cell packing (confluent layer of cells) was noted.

The same slides were then loaded onto the *MICRO21* and processed using the routine procedure as outlined in the Product Description. For each slide, up to 250 images were captured. The number of images captured varied depending on the cellularity of the specimen and preparation quality. Non-cellular images typically included stain precipitate, smudge cells and stained protein clumps which were recognized and discarded. The number of non-cells found was directly dependent upon the quality of the slide preparation and the nature of the specimen.

For differential analysis, two technologists independently reviewed the stored images for each specimen and classified all nucleated cells accordingly. In addition, any non-nucleated cells, micro-organisms, cell clustering or cell packing was also recorded if present.

In order to provide an accurate correlation measurement between the *MICRO21* and the Manual Methods, an equivalent number of cells was used for comparison analysis. The number of cells used for the comparative analysis was determined by cells counted by the *MICRO21*.

### **Conclusion**

The method verification and sensitivity, precision and correlation testing performed in the Test Methods confirm the safety and effectiveness of the *MICRO21* with CSF for the intended use of performing cytological analysis by locating, digitally storing and displaying nucleated cells in human Cerebrospinal Fluid preparations.



Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

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

SEP 16 1997

Re: K971470/S1  
Trade Name: MICRO 21™ with Cerebrospinal Fluid  
Regulatory Class: II  
Product Code: JOY  
Dated: July 21, 1997  
Received: July 22, 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.

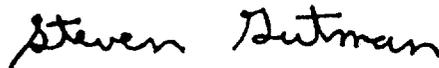
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770)488-7655.

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

510(k) Number (if known): K971470

Device Name: *MICRO21*<sup>™</sup> with Cerebrospinal Fluid

Indications for Use:

For In Vitro Diagnostic Use

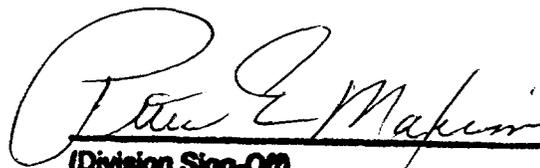
Intelligent Medical Imaging, Inc.'s *MICRO21*<sup>™</sup> with Cerebrospinal Fluid (CSF) is a laboratory instrument used to perform cytological analysis by locating, digitally storing and displaying nucleated cells in human cerebrospinal fluid preparations. Examination of cellular morphology and classification must be performed by qualified individuals.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_  
(per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_  
(Optional Format 1-2-96)



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