AUG - 7 1998

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Intelligent Medical Imaging, Inc.•

K982301

510(k) Summary

Assigned 510(k) number : _____

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and CFR 807.2.

Designated Point of Contact:	R. Otto Stellner
Title:	Vice President, Regulatory Compliance
Project Management	Susan M. Steele BSMT
Title:	Product Development Laboratory Coordinator
	Sean D. Murphy, Ph.D.
Title:	Product Development Technical Coordinator
Date:	Tuesday, June 30, 1998
Trade Name:	*MICRO21*® with Urine Sediment Analysis
Classification Name:	Automated Cell Locating Device
Classification Number:	81JOY
Class:	II
Regulation Number:	864.5260

Intended Use

For In Vitro Diagnostic Use

Intelligent Medical Imaging, Inc.'s *MICRO21®* with Urine Sediment Analysis is a laboratory instrument for locating, digitally storing and displaying microscopic fields of view from urine sediments in a urine slide for examination by a qualified individual for use in reporting a urine microscopic result.

Description:

The ***MICRO21*** with Urine Sediment Analysis, is an automated microscopic system that locates formed elements of urine sediment, digital stores images of the constituents and displays the images in an organized manner to aid technologists in performing an Urine Sediment Analysis procedure. The ***MICRO21*** process is substantially equivalent to the manual microscopic process.

A summary of the ***MICRO21*** with Urine Sediment Analysis process is as follows:

1. Patient urine samples are prepared by a technologist pouring off 12 mL of fresh urine into a centrifuge tube and capping the tube.
2. Each capped tube is then centrifuged at a relative centrifugal force of 400 for 5 minutes; approximately 1500 revolutions per minute with a 6 inch rotor radius (NCCLS Protocol GP 16-A).
3. The tubes are then removed from the centrifuge without disturbing the sediment, uncapped and decanted to 1 mL.
4. After resuspending the sediment, 20 µl of commercial urine sediment stain (Sternheimer-Malbin) are added to the sediment and mixed. Herein referred to as Stained Sample.
5. One drop of the stained sample is placed into the designated well of the urine slide. The urine slide can hold up to 8 individual stained samples.
6. The technologist then enters the test order into the *MICRO21* Review station Order Entry Screen, prints a barcode and places it on the urine slide. The barcode corresponds to the urine slide and wells allocated for the individual samples.
7. The *MICRO21* captures a minimum of 40 microscopic images, 16 at 100x magnification, 16 images at 200x magnification, and 8 images at 400x magnification, digitizes the images and stores them for display on a color monitor for review by a technologist.

8. The technologist reviews the images and quantifies the results.
9. A report of the results for each patient is printed.

Effectiveness Testing

To demonstrate the validity of the procedure, performance testing was conducted to assess the instrument's precision, accuracy, linearity, and correlation with the manual method. A summary of each is presented.

Test Method 1: Precision

To confirm instrument precision, a stained specimen sample from one preparation was processed and reviewed 5 times on the *MICRO21*. Three specimens, one each from a low, normal and high range were tested. The results were reviewed and recorded for each samples.

Test Method 2: Reproducibility

To confirm linearity, specimens containing reportable ranges for RBC's, WBC's and squamous epithelial cells were processed and reviewed on the *MICRO21*. RBC and WBC were recorded at 200x magnification. Squamous epithelial cells were recorded at 100x magnification. Selected highly concentrated specimens were used anddilutions of the specimen were made to obtain ranges. The results were reviewed and recorded for each sample.

Test Method 3: Linearity

To confirm linearity, specimens containing reportable ranges for RBC's, WBC's and squamous epithelial cells were processed and reviewed on the *MICRO21*. The results were reviewed and recorded for each sample.

Test Method 4: Correlation

The *MICRO21* with Urine Sediment Analysis results were compared to the manual urine microscopic reference method using standard correlation statistics. Results are reported as number of formed elements per reportable range, as recommended by NCCLS in GP16-A, Urinalysis and Collection, Transportation, and Preservation of Urine Specimens, Approved Guideline. For quantitative results, the average value from each range was used for computing the regression analysis values. For quantitative items, R^2 values were used to demonstrate correlation. For qualitative results, correlation or equivalence was determined to be within one reporting range of each other, as recommended in NCCLS GP16-A, section 2.3.2 Microscopic Urinalysis.

There were 182 stained samples were analyzed both manually and on the*MICRO21* by three certified medical technologists. To generate a wider range of urinary constituents, 31 stained samples were created using serial dilution and enrichment. Using blinded experimental methods, the stained samples were reviewed manually, and processed by the*MICRO21* and resultant images reviewed by the technologists.

Conclusion

There was no significant variation in the precision, reproducibility, and linear testing demonstrating the method. Correlation was demonstrated for RBC, WBC, Squamous Epithelial cells, Hyaline Casts, Non-hyaline Casts, Amorphous, Calcium Oxalate, and Triple Phosphate Crystals, Mucous, Sperm and Yeast. The data presented support the claim that the*MICRO21* with Urine Sediment Analysis is safe and effective for it's intended use of locating, digitally storing and displaying microscopic fields of view from urine sediments in a urine slide for examination by a qualified individual for use in reporting a urine microscopic result.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG -7 1998

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

Re: K982301
Trade Name: MICRO21® with Urine Sediment Analysis
Regulatory Class: II
Product Code: JOY
Dated: June 30, 1998
Received: July 1, 1998

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 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.

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 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

510(k) Number (if known): K982301

Device Name: *MICRO21* with Urine Sediment Analysis

Indications for Use:

For In Vitro Diagnostic Use

Intelligent Medical Imaging, Inc.'s *MICRO21®* with Urine Sediment Analysis is a laboratory instrument for locating, digitally storing and displaying microscopic fields of view from urine sediments in a urine slide for examination by a qualified individual for use in reporting a urine microscopic result.

INTELLIGENT MEDICAL IMAGING, INC. DOES NOT PROMOTE THE USE, PROVIDE SUPPORT FOR, MAKE CLAIMS OF EFFECTIVENESS OF, OR ASSUME LIABILITY OF 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)

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

Carlos Mercer 8/5/98

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K982301