

K972141

AUG 25 1997

Supplement to K972141  
June 17, 1997  
(Amended on August 22, 1997)

Device Name:           The Yellow IRIS urinalysis workstation

**K. 510(k) summary statement**

This submission supports the position of increased sensitivity in the detection of abnormal microscopic content using The Yellow IRIS urinalysis workstation, an already existing commercial in-vitro diagnostic device, compared to what can be obtained both by individual surrogate measures carried out on urine test strips and combinations of their measures in popular screening algorithms.

It reports a study which comprises comparisons of detection of microscopic abnormalities in a population of more than 18,000 abnormal urine specimens by dipstick screening and by visual observation of flow microscopy using The Yellow IRIS. The comparative measures were carried out among more than 100 clinical laboratories, in which both urine test strips and The Yellow IRIS are used to perform a complete routine urinalysis.

The Yellow IRIS shows 37.9%, 80.8%, and 555.5% greater sensitivity in the microscopic detection of abnormal numbers of red blood cells, (hematuria), white blood cells, (pyuria or leukocyturia) and bacteria (bacteriuria) in urine than does chemical detection by surrogate measures using urine test strips. The Yellow IRIS also finds 29.4% and 13.4% more specimens which contain abnormal compositions of red blood cells and/or white blood cells and/or bacteria content than does a three part and six-part dipstick screening algorithm, respectively.

4872-01



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
2098 Gaither Road  
Rockville MD 20850

Mr. Fred H. Deindoerfer  
President  
International Remote  
Imaging System, Inc.  
9162 Eton Avenue  
Chatsworth, California 91311

AUG 25 1997

Re: K972141  
Trade Name: The Yellow IRIS Urinalysis Workstation  
Regulatory Class: I  
Product Code: KQO  
Dated: June 3, 1997  
Received: June 6, 1997

Dear Mr. Deindoerfer:

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.

Page 2

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

Supplement to K972141  
June 17, 1997

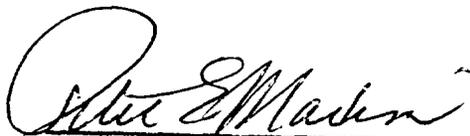
Device Name:           The Yellow IRIS urinalysis workstation

J. Indications for use

The Yellow IRIS is used by a competent human operator to produce a complete urinalysis profile, including chemistry, sediment microscopy and specific gravity determinations.

It is capable of detecting and reporting all types of formed urine sediment elements and of quantitating such elements, when desired, based on observed proportion of total particulate count.

The Yellow IRIS is intended to replace the conventional intensive manipulatively manual complete urinalysis procedure as well as the abbreviated.



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