

OCT 21 2002

International Remote Imaging Systems, Inc.
9162 Eton Avenue, Chatsworth, CA 91311
800-776-4747 818-709-1244 FAX 818-700-9661

510(k) SUMMARY

510(k) Submission: K022774

iQ™ 200 System

General Information:

Date of Submission: August 20, 2002

Trade Name of Device: iQ™ 200 System

Common Name of Device: Automated urinalysis system

Classification Name: Automated urinalysis system,
21 CFR 862.2900, Class I
Microscope, 21 CFR 862.3600, Class I
Automated cell counter (Urine particle counter),
21 CFR 864.5200, Class II

Submitter's Name: Harvey L. Kasdan, Ph.D.
Chief Scientist
Iris Diagnostics, A Division of
International Remote Imaging Systems, Inc.
9162 Eton Avenue, Chatsworth, CA 91311

RECEIVED
AUG 21 11 53 AM '02
FDA/CDRH/OCE/DMC

Indications for Use (Brief): The iQ 200 System is intended for analysis of urine chemistry, color, clarity, specific gravity, and formed sediment elements, which constitutes typical routine urinalysis.

Intended Use: The iQ 200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel and microscopic sediment analysis. Optionally, the iQ 200 Analyzer can be used as a stand-alone unit, or the results from the iQ 200 Analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

**Substantial Equivalence
to Predicate Devices:**

The iQ 200 System is substantially equivalent under Section 510(k) of the Food, Drug, and Cosmetic Act to The Yellow IRIS® Urinalysis Workstation with CHEMSTRIP® Reader, the IRIS Flow Microscope, the 900UDx Urine Pathology System, the 939UDx Urine Pathology System, and the Sysmex UF-100.

**Summary of
Technological
Characteristics:**

The iQ 200 System provides automatic sample handling for automated intelligent microscopy and automatic analyte classification for improved data reporting, presentation and management. Specimens are aspirated by an autosampler rather than poured manually. Each image is analyzed and assigned a classification by an auto analyte recognition algorithm. Using these classifications and the known observation volume, microscopic analyte concentrations may be automatically reported. If results from a specimen are not autoreported, microscopic examination results are displayed on an independent Computer WorkStation. Operators can then confirm or modify analyte classifications and release reports off-line for enhanced convenience, obviating the need to process a second aliquot for review. Chemistry results from the companion ARKRAY AUTION MAX AX-4280 are automatically consolidated by the Computer WorkStation for display and reporting.

Performance Studies:

Microscopic analysis performance of the iQ 200 System were compared with that of 939UDx Urine Pathology System and the Sysmex UF-100.

**Conclusions Drawn
From Clinical Tests:**

Clinical sensitivity (fraction of abnormal specimens detected) of the iQ 200 System exceeded that of the 939UDx Urine Pathology System and Sysmex UF-100, while clinical specificity (fraction of normal specimens detected) was comparable. The iQ 200 System generally had greater sensitivity for detection of individual microscopic formed elements than either the 939UDx Urine Pathology System or the Sysmex UF-100. With sensitivity for detection of each microscopic formed element fixed at 90%, iQ 200 System specificity was greater than that of either the 939UDx Urine Pathology System or Sysmex UF-100 for most formed elements. iQ 200 System automatically reported concentrations of RBC, WBC, squamous epithelial cells and casts matched those determined from expert human identification as well as the 939UDx Urine Pathology System predicate automatically reported concentrations matched those of the human expert when measured by the square of the regression correlation coefficient, R Square. The iQ 200 System has been shown to be suitable for its intended use.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 21 2002

Harvey L. Kasdan, Ph.D.
Chief Scientist
International Remote Imaging Systems, Inc.
9172 Eton Avenue
Chatsworth, California 91311-5874

Re: k022774
Trade/Device Name: iQ™ 200 System
Regulation Number: 21 CFR § 864.5200
Regulation Name: Automated Cell Counter
Regulatory Class: II
Product Code: LKM, KQO
Dated: August 20, 2002
Received: August 21, 2002

Dear Dr. Kasdan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

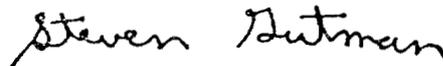
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2

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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer 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

PREMARKET NOTIFICATION

510(k) Number (if known): K022774

Device Name: iQ 200 System

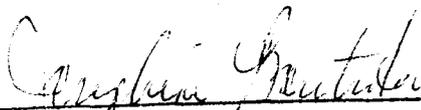
Indications for Use

The iQ 200 System is intended for analysis of urine chemistry, specific gravity, and formed sediment elements, which constitutes typical routine urinalysis.

Urinalysis is ordered by physicians as a screening procedure for detection of possible abnormal metabolic or systemic disease, indicated by chemical composition of urine, and of potential renal or urinary tract disease or dysfunction, indicated by urine concentration and by the nature and distribution of urinary formed elements. Urine profile testing is commonly employed in the initial clinical evaluation of patients admitted for hospital care or undergoing physical examinations.

Routine urinalysis is also indicated in diagnosis of patients with possible renal or urinary tract infection, carcinoma, or other injury, as well as for monitoring the status and effectiveness of drug, radiation, or dietary therapy, and of post-surgical or post-therapeutic recovery.

The information produced by the iQ 200 System concerning the composition of patient urines is ordered at the discretion of the physician, and is part of a larger body of laboratory and other test results available to assist the physician in health assessments or differential diagnoses. Routine urinalysis findings are always subject to judgment and interpretation by physicians relative to the patient's overall clinical presentation and history.



(Division Sign-Off)

Division of Clinical Laboratory Devices

510(k) Number

K022774