JUL 1 1 2003

510(k) Summary
for
AUTION™ JET AJ-4270 Urine Analyzer

1. SPONSOR

International Remote Imaging Systems, Inc.
9162 Eton Avenue
Chatsworth, CA 91311

Contact Person: William M. Dougherty
Manager
Quality Assurance and Evaluations
Telephone: 818-709-1244, ext. 140

Date Prepared: June 12, 2003

2. DEVICE NAME

Proprietary Name: AUTION™ JET AJ-4270 Urine Analyzer
Common/Usual Name: Urine Analyzer
Classification Name: Automated Urinalysis System

3. PREDICATE DEVICES

- Chemstrip 101 Urine Analyzer (K983510)
- AUTION MAX™ AX-4280 Urine Analyzer (K013783)
- Clinitek Atlas Automated Urine Chemistry Analyzer (K946183)

4. DEVICE DESCRIPTION

The AUTION™ JET AJ-4270 Urine Analyzer (AUTION™ JET) consists of an analyzer and accessories. ARKRAY also offers a hand-held Bar Code Reader for use with the AUTION™ JET. The AUTION™ JET Analyzer is designed for use only with the AUTION™ Sticks 10EA multi-parameter test strips.

5. INTENDED USE

The AUTION™ JET AJ-4270 Urine Analyzer (AUTION™ JET) is a semi-automated urine analyzer and is intended for use with the AUTION™ Sticks 10EA multi-parameter test strips for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite, leukocytes, and color. The AUTION™ JET Analyzer and AUTION™ Sticks 10EA test strips are intended for mutually exclusive use as a system.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The indicated use of the proposed and predicate urine analyzers is identical. All of these urine analyzers provide qualitative and semi-quantitative measurement of urine analytes using multi-parameter test strips for the measurement of the urine analytes.

The overall design of the proposed AUTION™ JET Analyzer is identical to the predicate Chemstrip 101 Urine Analyzer. Both of these analyzers are semi-automated, requiring that the user dip a test strip in the urine and place the test strip on a tray in the analyzer. The analyzers then time the reaction on the strip and automatically move the test strip to the Optical Block for analysis. The predicate AUTION MAX™ and Clinitek Atlas Analyzers are fully automated and contain mechanical systems for urine specimen handling and sampling in addition to those for test strip handling and analysis.

The proposed AUTION™ JET and the predicate Chemstrip 101 Analyzers use reflectance spectroscopy for the measurement of all urine analyte species. The proposed AUTION™ JET also uses reflectance spectroscopy for urine color determination. Urine color determination is not performed by the Chemstrip 101.

The predicate AUTION MAX™ and Clinitek Atlas Analyzers use reflectance spectroscopy for the measurement of all urine analyte species and urine color determination, with the exception of urine SG. The AUTION MAX™ and Clinitek Atlas Analyzers use the refractive index method for SG determination.

The AUTION™ JET is indicated for use with the AUTION™ Sticks 10EA multi-parameter test strips. The proposed AUTION™ Sticks 10EA are identical to the AUTION™ Sticks 9EB that are indicated for use with the predicate AUTION MAX™, with the exception that the AUTION™ Sticks 10EA test strips contain a reagent pad for SG determination. The AUTION™ Sticks 9EB do not contain a reagent pad for the measurement of SG. The AUTION MAX™ and Clinitek Atlas determine urine SG by the refractive index method.

The mechanisms of action for the chemical reactions used for the determination of urinary analytes, including glucose and occult blood, are similar for the proposed AUTION™ Sticks 10EA test strips and the predicate Clinitek Atlas reagent strips and Chemstrip 10UA test strips. The chemical constituents of the individual reagent formulations are similar for the proposed and predicate reagent pads, with minor differences in the choice of enzyme substrate and chromogens used for production of the colored endproduct.

7. PERFORMANCE TESTING

Several studies were conducted to evaluate the performance characteristics of the AUTION™ JET Urine Analyzer. A correlation study demonstrated excellent agreement when results from the AUTION™ JET were compared to those from a commercially available automated urine analyzer. Additional studies for precision and linearity demonstrated acceptable performance of the AUTION™ JET System for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 11 2003

International Remote Imaging System
c/o Ms. Cynthia J.M. Nolte, Ph.D., RAC
Staff Consultant
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: k030600
Trade/Device Name: AUTION™ JET AJ-4270 Urine Analyzer
Regulation Number: 21 CFR 862.2900
Regulation Name: Automated urinalysis system
Regulatory Class: Class I
Product Code: KQO; JIL; JIO
Dated: June 12, 2003
Received: June 13, 2003

Dear Dr. Nolte:

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 Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. 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 Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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 Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K030600

Device Name: AUTION™ JET AJ-4270 Urine Analyzer

Indications for Use:

The AUTION™ JET AJ-4270 Urine Analyzer (AUTION™ JET) is a semi-automated urine analyzer and is intended for use with the AUTION™ Sticks 10EA multi-parameter test strips for the in vitro measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite, leukocytes, and color. The AUTION™ JET Analyzer and AUTION™ Sticks 10EA test strips are intended for mutually exclusive use as a system.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division Sign-Off for Jean Cooper

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030600

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)