K060280

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JUN 13 2006

Iris

510(k) Summary

OWNER'S NAME AND ADDRESS

Iris Diagnostics, a Division of IRIS International Inc.
9172 Eton Avenue
Chatsworth, CA 91311

Primary Contact: Gerald J. Haddock, P.E.
Phone: (818) 709-1244 ext. 129
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Date of Summary: March 1, 2006

DEVICE NAME:

Proprietary Name: iChem 100™ Urine Chemistry Analyzer
Common/Usual Name: Urine Analyzer
Classification Name: Automated Urinalysis System

PREDICATE DEVICE:

ARKRAY AUTION JET ™AJ-4270 Urine Analyzer (k030600)

DEVICE DESCRIPTION:

The iChem™100 Urine Chemistry Analyzer is a semi-automated benchtop instrument for the rapid analysis of urine test strips. The iChem100 is designed to analyze and generate results for iChem10 SG Urine Chemistry Strips.

INTENDED USE:

The iChem™100 Urine Chemistry Analyzer is a semi-automated benchtop instrument for the rapid analysis of urine test strips. The iChem100 is designed to analyze and generate results for iChem 10 SG Urine Chemistry Strips only (Glucose, Protein, Bilirubin, Urobilinogen, pH, Specific Gravity,

INTENDED USE (CONTINUED):

Blood, Ketones, Nitrite, Leukocyte Esterase, Ascorbic Acid and Color). The iChem 100 is intended for use exclusively by healthcare professionals. The results obtained from the iChem 100 are useful in the evaluation of renal, urinary, and metabolic disorders

TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The indicated use of the proposed and predicate urine analyzers is the same. Both systems (instruments and associated strips) provide qualitative and semi-quantitative measurements of urine analytes using multi-parameter test strips.

The overall design of the proposed iChem 100 Urine Analyzer is very similar to the predicate. 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 proposed iChem 100 Urine Analyzer and the predicate AUTION JET™ AJ-4270 use reflectance spectroscopy for the measurement of all urine analytes. The proposed iChem 100 Urine Analyzer, and the predicate AUTION JET use reflectance spectroscopy for urine color determination. The proposed device implements the sensing function with a CMOS camera, compared to a photodiode used on the predicate device. Both units are microprocessor controlled.

The iChem 100 Urine Analyzer is indicated for use with iChem 10 SG Urine Chemistry test strips. The proposed iChem 10 SG strips are similar to the AUTION Sticks10EA that are indicated for use with the predicate AUTION JET AJ-4270, with the exception that the iChem 10 SG test strips contain a reagent pad for the measurement of Ascorbic Acid. The measurement of ascorbic acid on the iChem 100 is intended as a warning to the operator of potential interference with other tests due to elevated levels of ascorbic acid. The AUTION Sticks 10EA do not contain a reagent pad for the measurement of Ascorbic Acid

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 iChem 10 SG strips and the predicate AUTION JET™ 10 EA test strips.

PERFORMANCE TESTING

Non-clinical studies were conducted to evaluate the performance of the iChem 100 Automated Urine Analyzer. A correlation study demonstrated substantial equivalence when results from the iChem 100 were compared to the predicate device. Additional studies for precision and linearity demonstrated acceptable performance of the iChem 100 System for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Gerald J. Haddock P.E.
Director, Quality Assurance and Regulatory Affairs
Iris Diagnostics, a Division of IRIS International, Inc.
9172 Eton Avenue
Chatsworth, CA 91311

JUN 13 2006

Re: k060280
Trade/Device Name: iChem™ 100 Urine Chemistry Analyzer and iChem™ 10 SG strips
Regulation Number: 21 CFR§862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIO, JMA, JJB, JIN, JMT, CEN, JIR, CDM, JJQ, LJX, KQO
Dated: June 2, 2006
Received: June 3, 2006

Dear Mr. Haddock:

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 (240) 276-0484. 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/industry/support/index.html.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Division of Chemistry and Toxicology
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k060280

Device Name: iChem™ 100 Urine Chemistry Analyzer and iChem™ 10 SG strips

Indications For Use: The iChem100 Urine Chemistry Analyzer (iChem100) is a semi-automated benchtop urine chemistry analyzer intended for the *in vitro* measurement of the following analytes: glucose, protein, bilirubin, urobilinogen, pH, specific gravity, blood, ketones, nitrite, leukocyte esterase, ascorbic acid, and color. The iChem100 is intended for use only with iChem 10 SG Urine Chemistry Strips provided by Iris Diagnostics and is intended for use exclusively by healthcare professionals.

These measurements are useful in the evaluation of renal, urinary, and metabolic disorders.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

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