

510(k) SUMMARY**1. Submitter's Information:**

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Seoul, Korea
Tel: 213 267-1000
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510(k) Summary Prepared by:

Thomas J. Bouchard
mdi CONSULTANTS, INC.
55 Northern Blvd.
Great Neck, NY 11021
Tel: (516) 482-9001

2. Date 510(k) Summary Prepared: December 17, 1997

3. Name of the Device:

Trade or Proprietary Name: URiSCAN S-300 Semi-Automated Urine
Chemistry Analyzer

Common Name: Semi-Automated Urinalysis System

Classification Name: Automated Urinalysis System

4. Identification of legally marketed devices which the submitter claims equivalence.

The URiSCAN S-300 Semi-Automated Urine Chemistry Analyzer is substantially equivalent for purposes of Section 510(k) of the Federal Food, Drug and Cosmetic Act to the Ames/Miles, Inc. Clinitek 200 Semi-automated Urinalysis System (K842237), and the Boehringer Mannheim (Hitachi) Mditron Urine Analyzer system (K934042) in significant features, materials and intended use.

5. Description of the Subject Device:

The URiSCAN S-300 Semi-Automated Urine Chemistry Analyzer is a line operated unit which translates color and intensity of light reflected from reacted reagent pads into clinical units and displays the results. The instrument is specifically designed to "read" YEONGDONG URiSCAN urinalysis reagent strips (See K952307). The URiSCAN S-300 Semi-Automated Urine Chemistry system includes tests for the following physical properties and chemical constituents of urine: specific gravity, pH, Blood, Bilirubin, Urobilinogen, Ketones, Protein, Nitrite, Glucose, Leukocytes and Ascorbic Acid.

The instrument uses a light source produced by cold fluorescent lamp.

6. Intended Use of the Subject Devices:

The URiSCAN S-300 Semi-Automated Urine Chemistry Analyzer is a urine analyzer for detection of Occult Blood, Bilirubin, Urobilinogen, Ketones, Protein, Nitrite, Glucose, pH, Specific Gravity, Leukocytes and Ascorbic Acid in urine specimens through the reflectance method.

7. Technological Characteristics of the Subject Devices.

The URiSCAN S-300 Semi-Automated Urine Analyzer and each of the above mentioned urine chemistry analyzers used in the comparison are all desk top models that operate using the reflectance principal, have an LCD display and provide quantitative and qualitative test results. The URiSCAN S-300 uses a color CCD (Charge Coupled Device) technology whereas the other units use photo diode technology. The color CCD technology provides an analysis capacity over the entire visible wavelength, while the other units analysis capacity is limited to only certain wavelengths.

8. Discussion of Clinical Tests Performed:

The analytical performance of the URiSCAN S-300 Semi-Automated Urine Chemistry Analyzer on patient urine specimens was evaluated for precision, accuracy, linearity and correlation with the Ames/Miles, Inc.(Bayer) Clinitek 200 Semi-automated Urinalysis System and the Boehringer Mannheim Chemstrip Super UA Urine Analyzer predicate devices. Comparative clinical evaluations were also conducted at two different laboratories using a Clinitek 200+ system as a reference analyzer. The results of the clinical testing found the URiSCAN S-300 to perform similarly to the predicate devices.

9. Conclusions:

In summary, based on comparison with legally marketed devices and tests of this device to demonstrate compliance to EN 60601-1-2:1993, the subject URiSCAN S-300 is safe and effective and performs as well as the legally marketed predicate devices.



Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 10 1998

Yeongdong Pharmaceutical Corporation
C/O MDI Consultants, Inc.
Thomas J. Bouchard
55 Northern Boulevard
Great Neck, New York 11021

Re: K980047
URiSCAN S-300 Semi-Automated Urine Chemistry Analyzer
Regulatory Class: II
Product Code: KQO, JIL, LJX
Dated: April 14, 1998
Received: April 16, 1998

Dear Mr. Bouchard:

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 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.

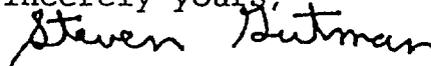
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Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

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 (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

510(k) Number (if known): _____

Device Name: URISCAN S-300 Semi-Automated Urine Chemistry Analyzer

Indications For Use:

Section 3 - Intended Use

The URISCAN S-300 Semi-Automated Urine Chemistry Analyzer is a urine analyzer for detection of Occult Blood, Bilirubin, Urobilinogen, Ketones, Protein, Nitrite, Glucose, pH, Specific Gravity, Leukocytes and Ascorbi Acid in urine specimens through the reflectance method.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of Clinical Laboratory Devices

510(k) Number K980047

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)