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K051034

510 (k) SUMMARY

Introduction

According to the requirements established in the Food and Drug Administration's guidance entitled "The New 510(k) Paradigm: Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications", the following information provides sufficient detail to understand the basis for a determination of substantial equivalence.

1) Submitter name, address, contact

MACHEREY-NAGEL GmbH & Co. KG
Valencienner-Strasse 11
D-52355 Dueren
GERMANY

Submitter's Name: Dietmar Czyron

Contact Person U.S.: Eduardo March
Phone: 301-838-3120 Facs.: 301-838-3182

Date Prepared: March 14, 2005

Proprietary Name:	URYXXON® 200
Common Name:	Urine Chemistry Analyzer
Classification Name:	System, Automated Urinalysis, 75KQO Class I ; Urinary Glucose Test System, 75JIL, Class II

3) Predicate device

We claim substantial equivalence to the currently market CLINITEK® 50 Urine Analyzer, manufactured by Bayer Corp. (K960546).

4) Device Description

The URYXXON® 200 Urine Analyzer is a reflectance photometer for in-vitro semi-quantitative reading of Medi-Test Combi 11 urine test strips for the following analytes: blood, urobilinogen, bilirubin, protein, nitrite, ketones, ascorbic acid, glucose, pH, specific gravity and leucocytes.

5) Intended use

In-vitro, semi-quantitative determination of urine analytes in clinical laboratories and point-of-use settings.

6) Comparison to predicate device

The table below indicates the similarities between the URYXXON® 200 Urine Analyzer and predicate devices, the CLINITEK® 50 Urine Analyzer and URYSIS 1100 Urine Analyzer

Topic	URYXXON® 200	CLINITEK® 50
Intend of Use	In-vitro semi-quantitative determination of urine analytes	Same
Scientific Technology	Reflectance Photometer	Same
Urine Test Strips	Medi-Test Combi 11 (K991927)	Bayer MULTISTIX® 10-SG
Test Parameters	Blood, urobilinogen, bilirubin, protein, nitrite, ketones, ascorbic acid, glucose, pH, specific gravity and leucocytes	Same, except ascorbic acid

7) Difference to predicate device	The URYXXON® 200 Urine Analyzer additionally measures ascorbic acid (vitamin C). Provides high-speed thermo-transfer printer.
8) Statement of Substantial Equivalence	MACHEREY-NAGEL has presented information of the technological principles, performance specifications, indications for use and results of clinical testing that demonstrate the substantial equivalence of the URYXXON® 200 to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Macherey-Nagel GmbH & Co. KG
c/o Mr. Eduardo March
Senior Consultant
AAC Consulting Group
7361 Calhoun Place, Suite 500
Rockville, MD 20855-2765

Re: k051034
Trade/Device Name: URYXXON 200
Regulation Number: 21 CFR 862.1340
Regulation Name: Urinary glucose (non-quantitative) test system
Regulatory Class: Class II
Product Code: JIL, JIP, CDM, CEN, JIN, JIR, JJB, JMA, JMT, KSL, LJX, KQO
Dated: October 21, 2005
Received: October 21, 2005

Dear Mr. March:

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): K051034

Device Name: URYXXON 200

Indications For Use:

The URYXXON® 200 is a portable reflectance photometer that instrumentally measures the reflectance off a reacted Medi-Test Combi 11 Reagent Strip for Urinalysis. The product is intended for use as an in vitro diagnostic aid using urine specimens for screening for diabetes, metabolic abnormalities, liver diseases, biliary and hepatic obstructions and diseases of the kidneys and urinary tract.

The test provided on Macherey-Nagel Reagent Strips for the determination of specific gravity, leucocytes, glucose, protein, blood, nitrite, pH, ketones, bilirubin, ascorbic acid and urobilinogen and urine color are considered routine urinalysis

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K051034

Prescription Use ✓ 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)