



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

FEB - 4 2005

Macherey-Nagel-Duren
c/o Eduardo March, RAC
AAC Consulting Group
7361 Calhoun Place
Suite 500
Rockville, MD 20855

Re: K991927

Trade/Device Name: Medi-Test Combi 11
Regulation Number: 21 CFR§862.1340
Regulation Name: Urinary glucose (nonquantitative) test system
Regulatory Class: II
Product Code: JIL, JIP, CDM, CEN, JIN, JIR, JJB, JMA, JMT, KSL, LJX
Dated: August 11, 1999
Received: August 12, 1999

Dear Mr. March:

This letter corrects our substantially equivalent letter of September 17, 1999 regarding missing product codes and primary regulation.

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 (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 additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, 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 continue 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,



Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter: Bardick Ellam International Marketing Manager Macherey-Nagel-Duren Valenciener Strasse 11 D-52355 Duren GERMANY	
Date Summary was Prepared	
Name Of The Device	Medi-Test Combi 11
Identification Of Predicate Device(s)	Bayer Multistix 10SG Dia Strip System, Calif. Immuno Diagnostics
Description of The Device	<p>The Medi-Test Combi 11 Reagent Strip for urinalysis is a dip-and-read test strip. The Medi-Test Combi 11 provides reagent areas on the strip for testing urine physiological parameters.</p> <p>The strip provides qualitative and semi-quantitative tests for specific gravity, leucocytes, glucose, ascorbic acid, protein, blood, nitrite, pH, ketones, bilirubin and urobilinogen by visual comparison with a color chart for each concentration range</p>
Intended Use	<p>The Medi-Test Combi 11 is a test strip for rapid determination of blood, urobilinogen, bilirubin, protein, nitrite, ketones, ascorbic acid, glucose, pH, specific gravity and leucocytes in urine.</p> <p>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 the urinary tract.</p>
Comparison of Device Characteristics to Predicate Device	The Combi 11 test strip is identical to the Dia Strip System's nine reagent tests and equivalent in performance to Bayer's Multistix 10SG. The Combi 11 adds the capability for screening for leucocytes and specific gravity of urine.

SUMMARY OF SAFETY AND EFFECTIVENESS

Non-clinical Testing	Non-clinical testing of the Combi 11 was not submitted.
Clinical Testing	<p>The Macherey-Nagel Combi 11 was investigated in actual clinical use by the Penn Elm Medical Group. The study was conducted during the normal course of providing patient care and included urinalyses for general physical assessment of asymptomatic patients and for patients presenting with specific diagnostic complaints. The study tested 100 randomly-selected urine samples from the clinic's patient population.</p> <p>The Penn Elm study indicates the Combi 11 had very similar results to the Bayer Multistix 10 for the reagent parameters.</p>
Conclusion	Medi-Test Combi 11 has intended and technological characteristics in common to both predicate devices. A clinical study demonstrated the clinical effectiveness of the added reagent strip areas for screening for leucocytes and specific gravity in urine. Therefore, the Combi 11 is substantially equivalent to the predicate devices.

DRAFT

June 4, 1999

510(k) Number (if known): K 991927

Device Name: **Medi-Test Combi 11**

Indications for Use:

The Medi-Test Combi 11 Reagent Strip for Urinalysis is a dip-and-read test strip. 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 strip provides qualitative and semi-quantitative tests for specific gravity, leucocytes, glucose, protein, blood, nitrite, pH, ketones, bilirubin, ascorbic acid and urobilinogen by visual comparison with a color chart for each concentration range.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratories
510(k) Number K 991927

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use:
(Per 21 CFR 80.109)

OR

Over-the-Counter Use: