K023626

510 (k) Number:

Device Name: AML HairCheck-DT (Cocaine)

Indications for use:

1. Intended Use and Indications for Use of the Subject Device:
   AML HairCheck-DT (Cocaine) is a process that utilizes the IDS One-Step ELISA Cocaine Kit in which head hair samples undergo forensic testing for the qualitative detection of cocaine at concentrations at or above 300 pg/mg hair for the purpose of identifying chronic cocaine use. This process has not been evaluated for use with hair specimens other than head. This process is intended exclusively for in-house professional use only. The process is not intended for sale to anyone.

   The **AML HairCheck-DT (Cocaine)** provides only a preliminary analytical test result. For a quantitative analytical result or for confirmation, presumptive positives are analyzed using a gas chromatograph - mass spectrometer operating in the selected ion monitoring mode using the deuterated internal standards. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are obtained.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X or Over-The-Counter-Use _____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K023626

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TX

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 1 2004

James Bourland, Ph.D.
Quest Diagnostics Incorporated
4230 Burnham Avenue
Las Vegas, NV 89119-5410

Re: k023626
Trade/Device Name: Quest Diagnostics HairCheck-DT (Cocaine)
Regulation Number: 21 CFR 862.3250
Regulation Name: Cocaine and cocaine metabolite test system
Regulatory Class: Class II
Product Code: DIO; DLJ: DIF
Dated: July 17, 2003
Received: July 21, 2003

Dear Dr. Bourland

This letter corrects our substantially equivalent letter of September 29, 2003. The trade name stated AML HairCheck-DT is corrected to Quest Diagnostics HairCheck-DT (Cocaine).

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 898. 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 Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

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 advice for your device on our labeling regulation (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-__. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Jean M. Cooper MS D.V.M

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