



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 14 2004

Dr. James Bourland
Technical Director
Quest Diagnostics, Inc.
4230 Burnham Ave.
Las Vegas, NV 89119

Re: k040257
Trade/Device Name: Quest Diagnostics Haircheck-DT (THC)
Regulation Number: 21 CFR 862.3870
Regulation Name: Cannabinoid test system
Regulatory Class: Class II
Product Code: LDJ
Dated: April 28, 2004
Received: May 5, 2004

Dear Dr. Bourland:

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.

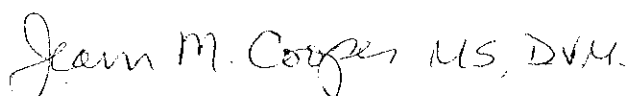
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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).

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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 (301) 594-3084. 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/dsma/dsmamain.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

Appendix 4

Indications for Use

510(k) Number (if known): K040257

Device Name: Quest Diagnostics Haircheck-DT (THC)

Indications For Use:

The QUEST DIAGNOSTICS HairCheck-DT (THC-COOH) is a bipartite device employing enzyme-linked immunosorbent assay (ELISA) for qualitative screening at 1.0 pg/mg of THC-COOH and Gas Chromatography - Mass Spectrometry - Mass Spectrometry (GC-MS-MS) for confirmation and the final quantitative reporting of THC-COOH in human hair samples for the purpose of identifying chronic marijuana 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. Clinical consideration and professional judgement should be applied to any drug of abuse test result.

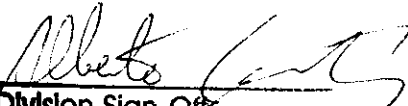
Prescription Use X
Counter Use _____
(Part 21 CFR 801 Subpart D)
Subpart C)

AND/OR

Over-The-
(21 CFR 807

(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**

510(k) K040257