DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 2 4 2002

Ms. Deborah N. Ballard
Quality Assurance Manager
MedTek, LLC
10315B Chapel Hill Road
Morrisville, NC 27560

Re: k022755
Trade/Device Name: LifeGuard™
Regulation Number: 21 CFR 864.6550
Regulation Name: Occult Blood Test
Regulatory Class: Class II
Product Code: KHE
Dated: August 19, 2002
Received: August 20, 2002

Dear Ms. Ballard:

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 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 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" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Steven Gutman

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

6.0 510(k) Statement (as required by 21 CFR 807.93)

I certify that in my capacity as the Manager of Quality Assurance for MedTek, LLC, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential information, as defined in 21 CFR 20.61.

Deborah N. Ballard

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August 19, 2002

Date

K022755

Premarket Notification [510(k)] Number

7.0 Indications for Use Statement

510(k) Number: K022755

Device Name: LifeGuard™

Indications for Use:

The LifeGuard™ is a guaiac-based test for the qualitative detection of occult blood in stool, which may indicate gastrointestinal disease. Patients can purchase the test without a prescription from stores or Internet distributors in order to perform testing at home. Users obtain their own stool samples by wiping onto the test device, then develop the tests, read the test results, and send a report of the results to their physician. LifeGuard™ is useful as an aid in the diagnosis of a number of gastrointestinal disorders and is used for colorectal cancer screening programs. The American Cancer Society recommends that at least three consecutive bowel movements be tested due to the irregularity of bleeding from some intestinal lesions. Therefore, the LifeGuard™ home test kit includes three test wipes for testing three closely spaced bowel movements.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022755