DEC - 9 2003

Tetracore, Inc.
11 Firstfield Road, Suite C
Gaithersburg, MD 20878

510(k) Summary

This 510(k) Summary of Safety and Effectiveness is being submitted in accordance with 21 CFR 807.02 and the Safe Medical Device Act of 1990.

The assigned 510(k) number is: K030370.

Date of Submission 4 February, 2003

Identification of Applicant

Applicant/Distributor:

TETRACORE, INC.
11 Firstfield Road, Suite C
Gaithersburg, MD 20878

Contact Person:
Beverly L. Mangold, Ph.D.
Tetracore, Inc.
11 Firstfield Road, Suite C
Gaithersburg, MD 20878
301.258.7553 (phone)
bmangold@tetracore.com (email)

Trade or Proprietary Name RedLine Anthrax Alert™ Test

Common Name *Bacillus anthracis* detection test

Classification Name Reagent; antibody; *Bacillus anthracis*

Classification Class II

Intended Use

The Tetracore RedLine Anthrax Alert™ Test is intended for the rapid, *in vitro* qualitative detection of *Bacillus anthracis* from non-hemolytic colonies obtained from sheep blood agar plates. The test is intended for use in clinical, public health, and hospital laboratories in conjunction with other markers and testing for the identification of *Bacillus anthracis*.

Device Description

The RedLine Anthrax Alert™ Test Cassette includes a reagent strip consisting of a combination of monoclonal and polyclonal antibodies that selectively detect the presence of *Bacillus anthracis* in aqueous specimens. The RedLine Anthrax Alert™ Test is supplied with single use test cassettes, Colony Isolation Buffer, and Positive Control reagent.

Substantial Equivalence

The RedLine Anthrax Alert™ Test is substantially equivalent to the following designated pre-amendment medical device:

Antibody-conjugate for the detection of Anthrax antigen

Technological Characteristics

Substantial equivalence is claimed to the designated pre-amendment medical devices as described at the Medical Devices Panel Meeting held March 7, 2002.

Performance Characteristics

The RedLine Anthrax Alert™ Test Kit was found to have a sensitivity of 99% based on the testing of 145 isolates and a specificity of 100% based on the testing of 59 isolates.

Stability

The Redline Anthrax Alert™ Test Kit is stable for twelve (12) months when stored at 15-30°C.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 9 - 2003

Beverly L. Mangold, Ph.D.
Tetracore, Inc.
11 Firstfield Road, Suite C
Gaithersburg, MD 20878

Re: k030370
Trade/Device Name: RedLine Alert™ Test
Regulation Number: Unclassified
Product Code: NPO
Dated: October 9, 2003
Received: October 9, 2003

Dear Dr. Mangold:

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 (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 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
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): k030370

Device Name: RedLine Alert™ Test

Indications For Use:

The Tetracore *RedLine Alert™* Test is an immunochromatographic test intended for the rapid, *in vitro* qualitative presumptive identification of *Bacillus anthracis* from non-hemolytic *Bacillus* colonies cultured on sheep blood agar plates. The test is intended for use in clinical, public health, and hospital laboratories in conjunction with other markers and testing for the presumptive identification of *Bacillus anthracis*.

Warning: The *RedLine Alert*™ Test has not been evaluated for use with spore preparations, suspicious powders, or samples other than colonies from culture growth.

Prescription Use ___x___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 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)

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K030370