NOV 1 8 2003

K032753

510(k) Summary of Safety and Effectiveness
Glucose Tolerance Beverage

Submitter
PERK Scientific, Inc.
520 Commerce Drive
Yeadon, PA 19050
Telephone: 610-259-1009
Fax: 610-284-4448

Contact Person
Mark Bartosh
President
Telephone: 610-259-1009
Email: markb@hydrolchemical.com

Date of Summary Preparation
September 4, 2003

Device Identification

Product Trade Name:	Glucose Tolerance Beverage
Device Name:	Drink, Glucose Tolerance
Classification:	II
Product Code:	MRV
Regulation Number:	862.1345

Device to Which Substantial Equivalence is Claimed
Trutol, Glucose Tolerance Test Beverage
Nerl Diagnostics, East Providence, RI
Legally marketed prior to May 28, 1976

Description of Device
Glucose Tolerance Beverage is a water-based flavored beverage containing specific quantities of dextrose.

Intended Use
As an accessory to an In Vitro Diagnostic Glucose Tolerance Test in the evaluation of diabetes mellitus and related disease conditions.

Performance Summary
Glucose Tolerance Beverage and the predicate device are similar with respect to intended use, size and technological characteristics. The product is manufactured using GMP to the specification ranges set by the World Health Organization and American Diabetes Association for such products. All products are independently certified as to the sugar composition and concentration.

Conclusion
Glucose Tolerance Beverage has the same intended use and characteristics as the predicate device. Moreover, independent testing demonstrates that the technological/packaging advances of the proposed device do not affect the characteristics of the contents and do not raise any new questions of safety or effectiveness. Glucose Tolerance Beverage is safe and packaging performance characteristics are substantially equivalent to or better than the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 2003

Mr. Mark Bartosh
President
PERK Scientific, Inc.
520 Commerce Drive
Yeadon, PA 19050

Re: k032753
Trade/Device Name: Glucose Tolerance Beverage
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: MRV
Dated: September 4, 2003
Received: September 5, 2003

Dear Mr. Bartosh:

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). 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,

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

Description of Device and Intended Use

Glucose Tolerance Beverage is a water-based flavored beverage with specific amounts of dextrose. The beverage is used as an accessory to an In Vitro Diagnostic Glucose Tolerance Test for the detection of glucose intolerance in the evaluation of diabetes mellitus and related disease conditions. The beverage is consumed by patients in a supervised setting and subsequent blood samples are drawn at specified time intervals. The tests are designed to measure the efficiency of the body to metabolize glucose. All contents other than water and dextrose are used strictly for flavoring and preservative characteristics and do not alter the overall dextrose content.

The proposed glucose tolerance beverage is designed to provide patients a safely packaged and pleasant tasting glucose load for the Oral Glucose Tolerance Test.

Note: Dextrose, CAS #50-99-7, is used interchangeably throughout the registration with Glucose, D-Glucose, Anhydrous Dextrose and Anhydrous Glucose.

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032753