OCT 27 2004

K042183

510K Summary of Safety and Effectiveness – Glucose Drink

Submitter
EverScientific, Inc.
7 Wetherill Lane
Chester Springs, PA 19425

Contact Person
Jay Reinhardt
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Date of Summary Preparation
04/19/04

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
GTB, Glucose Tolerance Beverage
Perk Scientific, Inc., Yeadon, PA

Description of Device
Glucose Drink is a water-based non-carbonated flavored beverage containing specific quantities of dextrose. We are marketing three flavors; orange, fruit punch, and lemon-lime. Each flavor will have glucose concentrations of 50, 75, 100 grams of D-glucose per 10 oz bottle.

Intended Use
The intended use is as an accessory to an In Vitro Diagnostic Glucose Tolerance Test in the evaluation of diabetes mellitus and related disease conditions.

Performance Summary
Glucose Drink 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. Additionally shelf life stability testing will be completed prior to marketing product.

Conclusion
Glucose Drink has the same intended use and characteristics as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

OCT 27 2004

Mr. Jay Reinhardt
Vice President of Product Development
Ever Scientific
7 Wetherill Lane
Chester Springs, PA 19425

Re: k042183
Trade/Device Name: Glucose Drink
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: MRV
Dated: July 28, 2004
Received: August 11, 2004

Dear Mr. Reinhardt:

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,

Jean M. Cooper MS, DVM

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

Indications for Use

510(k) Number (if known): **K042183**

Device Name: **Glucose Drink**

Indications For Use: **Glucose Drink is a flavored beverage containing specific amounts of dextrose (D-glucose). Manufactured beverages contain three different amounts of glucose; 50,75, and 100 grams quantities per 10 oz bottle. This product is consumed in the In Vitro Diagnostic Glucose Tolerance Test for the detection of glucose intolerance in the evaluation of diabetes mellitus and other related illnesses.**

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

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IFNEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

510(k) K042183