DEC 1 8 2003

5. 510(k) SUMMARY (Per 21CFR807.92)

June 27, 2003

K032029

Submitter Information
Contact Person: Debbie Cheng
Phone Number: 886-4-23508198 or 973-762-0516 (US)
FAX Number: 886-4-23508199

Trade Name:
BTg Smartest Glucose Test System

Common Name: Glucose test system

Panel: Clinical Chemistry 75

Product Code: NBW

Device Classification: Class II

Intended Use
The BTg Smartest Glucose test system is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Device Description
A chemical reaction between glucose in whole blood and the chemicals on the test strip produce a current. The meter measures the current and the meter calculates glucose concentrations from the current produced in the reaction.

Predicate Device Information- Statement of Substantial Equivalence
The BTg Smartest Glucose Test System is substantially equivalent to the Bayer Elite with the Ascensia Elite test strips, 510(k) Number: K991242.

Similarities and Differences (Predicate and Smartest BTG Glucose)

	ELITE	BTG
Similarities	1. Intended use: Monitors Glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test Principle: Principle includes measuring glucose by measuring a current produced by a chemical reaction. 4. Test Principle: Uses glucose oxidase reaction. 5. Measuring Range: 20 to 600 mg/dL.	1. Intended use: Monitors Glucose using whole blood. 2. Directly displays results without requiring calculation. 3. Test Principle: Principle includes measuring glucose by measuring a current produced by a chemical reaction. 4. Test Principle: Uses glucose oxidase reaction. 5. Measuring Range: 20 to 600 mg/dL.
	ELITE	BTG
Differences	1. Size: Meter is 97.8 x56 x14.5 mm. 2. Measuring time: 30 seconds.	1. Size: Meter is 115x 44 x 21, which is longer and slimmer, but thicker than the ELITE. 2. Measuring time: 15 seconds.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 1 8 2003

Ms. Debbie Cheng
BT Medical
6F-5 #210 38th Road
Taichung Industrial Park
Taichung
CHINA (TAIWAN)

Re: k032029
Trade/Device Name: BTg Smartest Glucose Test System
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: NBW; JJX
Dated: November 18, 2003
Received: November 20, 2003

Dear Ms. Cheng:

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

510(k) Number (if known): K032029

Device Name: **BTg Smartest Glucose Test System**

Indications For Use:

The BTg Smartest Glucose test system is intended for use in the quantitative measurement of glucose in whole blood. It is intended for use by healthcare professionals and people with diabetes mellitus at home as an aid in monitoring the effectiveness of a diabetes control program. It is not intended for the diagnosis of or screening for diabetes mellitus, and is not intended for use on neonates.

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ or Over-The Counter Use ✓
(Per 21 CFR 801.109)

Carol C. Benson for Jean Cooper, DVM
Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K032029