510(K) Summary, K100843

BRAIN TUNNELGENIX TECHNOLOGIES CORP
3000 Park Avenue
Bridgeport CT 06604
319-545-7377
Contact: Joseph Roger Titone, President
Date prepared: June 5, 2010

AUG 17 2010

1. **Trade Name: Abreu BTT 700 Skin Temperature System**
   Common Name: Thermometer, Electronic, Clinical

2. **Classification Name: FLL – Clinical Electronic Thermometer**
   Class of device: Class II.

3. **The legally marketed device to which we are claiming equivalence [807.92(a)(3)] : YSI Precision 4000 Thermometer, submitted by Yellow Springs Instrument, Inc. K910718**

4. **Description of device: The Abreu BTT 700 is a device used to measure the temperature of the skin by means of a thermistor coupled with an electronic signal amplification, conditioning, and display unit. As part of its basic design, the thermistor probe is an integral part of a non-disposable "Pen" (covered by a condom), and a disposable "finger." The components of the Abreu BTT 700 consist of a "pen", a disposable "finger", an Interface Module, and a USB A to USB mini cable. The Abreu BTT 700's Interface Module incorporates an onboard computer processing unit which is controlled by a permanently installed software program. Electronic signals received from the thermistor are processed in the Interface Module. With the aid of a computer assisted program, the output is a digital and analog temperature readout. The digital readout is in Celsius and Fahrenheit. The digital analog display is a 270° circular dial illustrating 16-40°C in tenths of a degree**

5. **Intended use: The Abreu BTT 700 System is intended for the continuous monitoring of skin temperature during surgical procedures, recovery room, intensive care, and general patient monitoring. The unit will alert the patient and/or hospital personnel when the monitored temperature exceeds or falls below pre-selected levels.**

6. **Technological characteristics: The Abreu BTT 700 is substantially equivalent to the YSI Precision 4000 Thermometer, submitted by Yellow Springs Instrument, Inc. K910718, in that it provides the following characteristics:-**
   Same thermistor detectors used in the design
   -Physical characteristics are essentially the same
   -Material composition is essentially the same
   -Same basic indications for use
   -Same presentation of temperature data.

Comparison Table

Characteristic	YSI4000 K910718	Abreu BTT 700
Indication for Use	Skin Temperature Measurement	SAME
Ambient Operating Temperature Range	0 to 50° C	SAME
Temperature Display Range	25 to 45° C	SAME
Accuracy	+/- 0.3° C Between 25 to 35° C +/- 0.2° C Between 35 to 37° C +/- 0.1° C Between 37 to 39° C +/- 0.2° C Between 39 to 41° C +/- 0.3° C Between 41 to 45° C	SAME
Resolution	0.1° C	SAME
Display	LCD	Computer Monitor
Probes	Various	Abreu BTT 700 Temperature pen with disposable coverlet or BTT Forehead Finger Sensor
Technology	Precision PTC Thermistor 2250 ohms., enclosed in metal capsule	Precision PTC Thermistor 10 K instead of a 2250 ohm thermistor in order to reduce the size of the contact area of the sensing probe isolated with medical grade acrylic
Probe Power	30 microwatts or less	SAME
Target Population	Adults and children	SAME
Conditions of Use	Doctors and Health Care Professionals	SAME
Alarm Settings	Independent HI and LO (low) alarm settings, user adjustable, flash and audio alerts	SAME
Computer Connection	Not available	USB
Error indications	No probe Under Range Over Range	SAME with the addition of a Shorted Probe detector
Self Check Function	Every temperature scan includes reading the value of an internal precision resistance (37.1° C) checking conversion process	SAME
Power Source	Internal battery	USB port, 5 volts @ 175 ma.

7. Performance: Laboratory and clinical testing has verified electrical safety, electromagnetic compatibility, and accuracy in the clinical environment. Clinical testing was performed on subjects of different age groups: adults, geriatric, and pediatric with results showing performance equivalent to or better than the predicate. There were no adverse events.

8. Conclusion and Summary: The comparison of technological characteristics, test results, and the indications for use leads to the conclusion that there are no new issues of safety or effectiveness leading to the conclusion of substantial equivalence with the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Brain Tunnelgenix Technologies Corporation
C/O Mr. Daniel Kamm
Kamm & Associates
8870 Ravello Court
Naples, Florida 34114

AUG 17 2010

Re: K100843
Trade/Device Name: Abreu BTT 700 System
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: July 28, 2010
Received: August 4, 2010

Dear Mr. Kamm:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K100843

510(k) Number (if known): K100843

Device Name: Abreu BTT 700 System

Indications For Use:

The instrument is for the continuous monitoring of skin temperature during surgical procedures, recovery room, intensive care, and general patient monitoring. The unit will alert the patient and/or hospital personnel when the monitored temperature exceeds or falls below pre-selected levels.

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 IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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