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

Truer Medical Incorporated
C/O Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services, LLC
1394 25th Street, NW
Buffalo, Minnesota 55313

NOV 18 2010

Re: K101244
Trade/Device Name: General Purpose Probes, Tympanic Probes, Skin Sensing Probes,
Regulation Number: 21 CFR 880.2910
Regulation Name: Clinical Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: October 30, 2010
Received: November 3, 2010

Dear Mr. Job:

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

K101244

NOV 18 2010

Indications for Use Statement

510(k) Number (if known): not assigned

Device Name: General Purpose Probes, Tympanic Probes, Skin Sensing Probes

Indications for Use:
The intended use of the temperature probes is to measure temperature by a resistor that is sensitive to temperature changes. The probe is connected to the patient monitor by using an interconnect cable. These probes have skin or core contact with a patient.

Skin probe (SSP 400 and SSP 700): The Skin Sensor Probe is indicated for use in the routine monitoring of skin temperature. It is individually packaged. The skin temperature probe is designed for use with Data Scope, Protocol and DeBusk monitoring systems and other monitors capable with 400 Series temperature probes. The device is indicated for use by qualified medical personnel only.

GP Probes (GP 9400, GP 9700 and GP 14400): The General Purpose Temperature Probe is intended for continuous temperature monitoring. The probe is inserted into the nasopharynx, mouth or the rectum. It is individually packaged. The temperature probe beneath the cuff at the distal tip is designed for use with Data Scope, Protocol and DeBusk monitoring systems and other monitors capable with 400 Series temperature probes. The device is indicated for use by qualified medical personnel only.

Tympanic Probe (TP 400 and TP 700: The Tympanic Probe is intended for monitoring patient temperature through the outer auditory ear canal. It is individually packaged. The tympanic Probe is designed for use with Data Scope, Protocol and DeBusk monitoring systems and other monitors capable with 400 Series temperature probes. The device is indicated for use by qualified medical personnel only.

Prescription Use X AND/OR Over-The-Counter Use_____
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for RZC

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

510(k) Number: K101244