Section 11: 510(k) Summary

In accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 of the Code of Federal Regulations Part 807 (21 CFR § 807), and in particular §807.92, the following summary of safety and effectiveness information is provided:

Submitted By

MAY 0 6 2003

Debra L. Jackson, RAC
Senior Manager, Quality Assurance & Regulatory Affairs
Welch Allyn, San Diego
7420 Carroll Road
San Diego, California 92121

Telephone: (315) 685-4133
Contact: Dave Klementowski
Date Prepared: February 21, 2003

Device Name

Common or usual name: Thermometer, Electronic Thermometer, Predictive Thermometer

Classification
Class: II
Panel: 80
Procode: FLL - clinical electronic thermometer

Predicate Devices

The SureTemp® Plus clinical electronic thermometer consists of an elongated metal heat-conductive probe connected to the thermometer's main body through a coiled cord. The probe contains a thermistor that conveys temperature information to the main body for calculation of patient temperature.

Prior to use, a plastic probe cover must cover the probe. This cover must not be a significant barrier to the transfer of heat from the patient to the probe body (and thermistor). In addition, the disposable nature of the probe cover prevents microbiological cross-contamination among patients which might occur with a re-useable probe. Calculation of patient temperature may (in the normal or predictive mode) utilize algorithms that enable accurate temperature prediction within 4 to 15 seconds of probe placement (times vary based on the temperature mode selected).

There are two model designations for the SureTemp® Plus and they are the Model 692 and 690. The Model 690 is the lower cost version of the Model 692 and does not include the backlit display and security features or pulse timer.

Device Description

The SureTemp® Plus clinical electronic thermometer consists of an elongated metal heat-conductive probe connected to the thermometer's main body through a coiled cord. The probe contains a thermistor that conveys temperature information to the main body for calculation of patient temperature.

Prior to use, a plastic probe cover must cover the probe. This cover must not be a significant barrier to the transfer of heat from the patient to the probe body (and thermistor). In addition, the disposable nature of the probe cover prevents microbiological cross-contamination among patients which might occur with a re-useable probe. Calculation of patient temperature may (in the normal or predictive mode) utilize algorithms that enable accurate temperature prediction within 4 to 15 seconds of probe placement (times vary based on the temperature mode selected).

There are two model designations for the SureTemp® Plus and they are the Model 692 and 690. The Model 690 is the lower cost version of the Model 692 and does not include the backlit display and security features or pulse timer.

Intended Use

The Welch Allyn SureTemp® Plus thermometer enables the health care professional to make an accurate prediction of a febrile, afebrile or hypothermic patient's oral temperature in approximately 4-6 seconds (in Normal mode). Pediatric Axillary (age 17 and younger) temperatures can be obtained in approximately 10-13 seconds. Adult Axillary temperatures (in Normal mode) can be obtained in approximately 12-15 seconds. Rectal temperatures (in Normal mode) can be obtained in approximately 10-13 seconds. Normal (predictive) mode is available for oral, rectal, and axillary use.

In the Monitor mode, the instrument provides the capability of accurate, long-term monitoring of actual oral, rectal or axillary temperature, and of following the temperature whether constant, increasing, or decreasing.

The SureTemp is a clinical grade thermometer intended for use by healthcare practitioners only; typically in a hospital, clinic, long- term care, or mobile health care environment. It is not intended for home use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 0 6 2003

Ms. Debra L. Jackson
Senior Manager, QA/RA
Welch Allyn, Incorporated
7420 Carroll Road
San Diego, California 92121

Re: K030580
Trade/Device Name: SureTemp® Plus
Regulation Number: 880.2910
Regulation Name: Electronic Thermometer
Regulatory Class: II
Product Code: FLL
Dated: February 21, 2002
Received: February 24, 2003

Dear Ms. Jackson:

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 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); 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.

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 advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. 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,

Susan Runner

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K030580

DEVICE NAME: SureTemp® Plus

INDICATIONS FOR USE:

The Welch Allyn SureTemp® Plus thermometer is intended to be used by healthcare professionals, to provide an accurate prediction of patient temperature using the oral, axillary or rectal body sites in 4 to 15 seconds, or to provide an actual temperature reading in the continuous monitor mode in about 3 minutes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ (Per 21 CFR 801.109)

OR

Over-The-Counter-Use ✓ (Optional Format 1-2-96)

Patricia Cucuzza

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

510(k) Number: K030580