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Summary of Safety and Effectiveness

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Proprietary Name: OxiTemp, 3301T SA
Common/Classification Name: Oximeter with Ear Thermometer
Predicate Devices: BCI 3301T OxiTemp and Exergen Ototemp

New Device Description:

The OxiTemp, 3301T SA, pulse oximeter is an updated version of existing 3301T OxiTemp legally marketed by BCI International. The updated device provides all the features of the 3301T plus provides tympanic temperature measurement and extends the ambient operating temperature range.

Intended Use

The 3301T OxiTemp provides fast, reliable SpO₂, pulse rate and temperature measurements. It can be used in the hospital or clinical environment, and during emergency air or land transport. The oximeter will operate accurately over an ambient temperature range of 32 to 110° F (0 to 43° C). The IR ear thermometer uses a patented ambient temperature compensation technique that allows it to provide accurate patient temperatures over the ambient temperature range 60 to 110° F (16 to 43° C). Below 16°C (60°F) a low ambient message is displayed. The 3301T SA OxiTemp extends the ambient temperature range the device can operate in up to 130°F (54°C) and down to 32°F (0°C).

The oximeter works with all BCI oximetry probes providing SpO₂ and pulse rate on all patients from neonate to adult (see the section CHOOSE THE PROBE under USING THE OXIMETER in the operations manual). For the 3301T the IR ear thermometer must seal the ear canal opening and look into the ear canal to provide an accurate temperature measurement. Therefore, it is restricted to patients over two years of age. The 3301T SA provides tympanic temperature measurements. The probe must be able to fit into the ear canal for proper operation. Therefore, it is restricted to patients over three years of age.

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Performance Data:

Testing of the 3301T SA OxiTemp and the predicate devices (BCI 3301T oximeter and the Exergen OtoTemp HTTS-3000-SD) was done to show that the performance of the 3301T SA was equivalent to the predicate devices. The first test showed that the oximeter portion of the OxiTemp would operate properly at a temperature of 130°F. The device was put into an oven for almost eight hours. Approximately 4.5 hours were spent at 130°F.

The second test showed that the 3301T SA would correctly operate and track the temperature of a target up to 130°F. The ambient and target temperatures were the same. The 3301T SA was in the environmental chamber during the entire test.

The third test showed that the 3301T SA would read a patient (target) temperature of approximately 98.6°F in ambient temperatures up to 130°F.

The fourth test showed that the 3301T SA would read a patient (target) temperature of approximately 98.6°F in an ambient temperature of 32°F.

The fifth test showed that the 3301T SA would measure a target temperature over the specified range of 65°F to 110°F. It was compared to the predicate device, the OtoTemp HTTS-3000-SD.

The last test was comparing readings between the two devices on 34 people. The first comparison was on ear to ear measurements for the 3301T SA.. The last test also compared the OxiTemp and an OtoTemp in reading temperature on the right ear. The device performed within the 1.0°F (two standard deviation, 95.45% population) specification for both comparisons. Statistical methods were used because of the technique sensitivity of tympanic temperature measurements.

The Oxitemp passed all the tests.

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Respectfully,



Donald Alexander
VP Regulatory Affairs

