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## Summary of Safety and Effectiveness

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

### New Device Description:

The 3301T Oxitemp, with the 3341 series pediatric temperature probes, is an updated version of the existing 3301T OxiTemp, with the 3340 series adult temperature probes, legally marketed by BCI International. The updated device provides all the features of the 3301T plus provides pediatric IR ear temperature measurement.

### Intended Use

The OxiTemp provides fast, reliable SpO<sub>2</sub>, 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 oximeter works with all BCI oximetry probes providing SpO<sub>2</sub> and pulse rate on all patients from neonate to adult. The IR ear thermometer must seal the ear canal opening and look into the ear canal to provide an accurate temperature measurement. Therefore, the adult size temperature probe (3340 series) is restricted to patients over two years of age. The pediatric size temperature probe (3341 series) is restricted to patients over one month of age.

## Performance Data:

The first bench test showed that the 3301T with the 3341 series pediatric temperature probe would measure a target temperature over the specified range of 60°F to 110°F. It was compared to the predicate device, the OtoTemp LighTouch LTXP-1. Two targets were used, a floating black body (106°F to 70°F) and a black plastic block that was put in an oven (115°F) then into a refrigerator freezer (less than 32°F). The measured temperature range of the block was 61.2°F to 109.9°F. The largest difference between measurements was 0.2°F with the allowable difference being 0.4°F. This test showed that the 3301T with the pediatric temperature probe would read the same temperature as the Exergen LTXP-1 (the standard).

A second bench test was run comparing the 3301T with the 3341 probe to the other predicate device, the 3301T with the 3340 adult probe. A floating black body was used as the target (109°F to 73°F). The largest difference between measurements was 0.1°F with the allowable difference being 0.4°F. This test showed that the 3301T with the pediatric temperature probe would read the same temperature as the 3301T with the 3340 adult probe.

The next series of tests were comparing ear to ear & device to device readings using the 3301T with the pediatric temperature probe. Ear to ear measurements are used to verify accurate temperature measurements (repeatability) and proper user technique. The device to device testing was to show that the 3301T with the pediatric temperature probe operated in a similar manner to the predicate devices when used properly.

The first test of ear to ear comparisons was done on 24 children from 6 months to 10 years of age. It was used to determine if the user had enough experience to properly use the device and continue on to the next series of tests. The ear to ear difference should all be in the order of 0.5°F or less. All measurements except one met that criteria, with the maximum difference being 0.6°F. With only one measurement being just out of the desired range it was decided that the user (recently trained) had enough experience to continue with the device to device testing.

The first device to device testing compared the 3301T with the pediatric probe to the Exergen LighTouch. The test was run on 11 children, ages 1 to 9 years of age. All ear to ear & device to device (same ear) differences should be 0.5°F or less. All measurement differences, ear to ear & device to device, were 0.5°F or less.

The next device to device testing compared the 3301T with the pediatric probe to the 3301T with the adult temperature probe. The test was run on 9 children, ages 7 to 13 years of age. All ear to ear & device to device (same ear) differences should

be 0.5°F or less. All measurement differences, ear to ear & device to device, were 0.5°F or less.

The last test compared the 3301T with the pediatric probe to the 3301T with the adult temperature probe on adults. The test was run on 15 adults, all greater than 20 years of age. This test was to demonstrate that the probe tip must seal the ear canal and not enter it, with the expected difference criteria going up to 1.0°F. All of the ear to ear measurement differences using the adult probe were less than 0.5°F (as expected). The results with the pediatric probe met the defined criteria (1.0°F differences) with a maximum difference of 0.8°F. It was interesting to note that over half ( 8 of 15 ) subjects had readings that met the previous 0.5°F difference specifications for ear to ear & device to device comparisons (got the same temperature on an adult). One adult had small ears and only allowed the pediatric probe to be used.

This shows that measurements taken with the pediatric 3301T are accurate and repeatable. The pediatric 3301T performed within the expected criteria when compared to the predicate devices.

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,

A handwritten signature in black ink that reads "Donald Alexander". The signature is written in a cursive style with a large, prominent initial "D".

Donald Alexander  
VP Regulatory Affairs