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Summary of Safety and Effectiveness

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Prepared:	May 31, 1996
Proprietary Name:	3304 Pulse Oximeter
Common/Classification Name:	Pulse Oximeter
Predicate Devices:	BCI 3301, 3302 & 3100 Oximeters

New Device Description:

The new BCI 3304 pulse oximeter is an updated version of existing pulse oximeters legally marketed by BCI International. This updated device is designed to provide full featured monitoring capabilities in a light weight, transportable design. The system consists of a small table top oximeter with a wall mount charger. The system features an SpO_2 probe interface, display of patient data via an LED display (SpO_2, Pulse Rate, Pulse Strength), system status LEDs (Probe, Lo Batt, Silence, Alarm, Artifact, Search), and the function keypad area consisting of eight keys (O/I, ID/Clear, Up and Down Arrows, Alarm Select, Alarm Silence, Alarm Volume, Pulse Volume). The oximeter has a printer / pc port that is used for data communication, an optional analog output and an optional digital alarm adapter for a remote location.

Intended Use:

The 3304 provides fast, reliable SpO_2, pulse rate and pulse strength measurements. It may be used in the hospital or clinical environment, during emergency air or land transport and in the home. The oximeter will operate accurately over an ambient temperature range of 32 to 104° F (0 to 40° C). The oximeter works with all BCI oximetry probes providing SpO2 and pulse rate on all patients from neonate to adult. The oximeter permits continuous patient monitoring with adjustable alarm limits as well as visible and audible alarm signals.

Performance Data:

The design of this device utilizes currently available technology found in many legally marketed devices. Testing was done to ensure that it would perform within the environment(s) for which it is to be marketed. The testing was performed in accordance with the guidelines and standards found in the reviewers guide for respiratory devices. This testing included EMC, electrical, mechanical durability, safety (operator and patient), and temperature/humidity. The results of the testing demonstrated that the device was in compliance with the guidelines and standards referenced in the reviewers guide and that it performed within its specifications and functional requirements.

Additionally, clinically controlled desaturation studies were done to demonstrate that the 3304 accurately displays the patient's blood oxygen level within its accuracy limits as compared to a co-oximeter (OSM-3). Statistical analysis on the data collected from the studies were compared to those from a co-oximeter during the controlled subject desaturation runs. The results from the clinical studies support the accuracy claims of the device, with a standard deviation of 1.92 for the measurement range of 70-100% and 2.31 for the range of 50-69%. The R squared value was 0.978 over the entire range. (R squared - measure of how true the regression line is. R squared = 1 is a perfect fit.) On the basis of these results and the above-referenced testing it is our determination that the device is safe, effective, and performs as well as or better than the legally marketed predicate device(s).

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

Donald Alexander
VP Regulatory Affairs