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## Summary of Safety and Effectiveness

Submitter: BCI International, Inc.  
Address: W238 N1650 Rockwood Drive  
Waukesha, WI 53188

Telephone: (414) 542-3100  
Contact: VP Regulatory Affairs

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Proprietary Name: Capnocheck<sup>®</sup> Plus, Model 9004  
Common/Classification Name: Capnograph  
Predicate Devices: BCI 9000 Capnograph-Oximeter  
BCI 9100 Multigas Monitor

### New Device Description:

The BCI Capnocheck Plus capnograph with optional pulse oximetry (SpO<sub>2</sub>) and fractional inspired oxygen (FiO<sub>2</sub>) is an updated version of existing devices 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 capnograph with a wall mount charger. The system features a gas inlet port with moisture trap for the breath sample (sidestream capnograph), an SpO<sub>2</sub> probe interface, the FiO<sub>2</sub> sensor connector, display of patient data via a VFD display (CO<sub>2</sub>, SpO<sub>2</sub>, Pulse Rate, Pulse Strength, FiO<sub>2</sub>, alarm information), system status LEDs (Battery, Alarm Silence, Alarm, & Alert), and the function keypad area consisting of six keys (STNBY/ON, WAVE/TREND, Up and Down Arrows, MENU/ENTER, & Alarm Silence). The capnograph has a serial printer / pc port that is used for data communication. Three analog output channels are supported on the same connector.

### Intended Use:

The 9004 may be used in the hospital or clinical environment, and during emergency land transport. It is not intended for use in the home. It is intended to be used in all critical environments, including ventilatory applications, patient transport and anesthesia environments. The oximetry option works with all BCI oximetry probes providing SpO<sub>2</sub> and pulse rate. The patient population is defined to be pediatric to adults.

The 9004 permits continuous patient monitoring with adjustable alarm limits as well as visible and audible alarm signals. It is not intended or designed to be used as an apnea monitor.

The 9004 will operate accurately over an ambient temperature range of 32 to 122° F (0 to 50° C).

**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.

Performance testing between the new 9004 and the predicate 9000 was done to show that the performance of the two devices is the same (CO<sub>2</sub>, RR, SpO<sub>2</sub> & HR). All the results of each parameter of each device were the same or within one count of each other.

An in-house performance test of the 9004 was run. It tested CO<sub>2</sub> response time, accuracy & linearity with humidity & over temperature & at altitude, temperature shock, interfering gases, breath rate, contamination and water trap testing. The testing to determine how often the unit needs to be recalibrated was also completed. The FiO<sub>2</sub> function was tested with O<sub>2</sub> values of 0%, 21%, 60% and 100% oxygen. The 9004 passed all the tests.

Additionally, clinically controlled desaturation studies of the optional oximeter were done to demonstrate that the 9004 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 2.0 for the measurement range of 70-100% and 2.7 for the range of 50-69%. The R squared value was 0.97 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  
VP Regulatory Affairs