K070259

510(k)

FEB 21 2008

Summary of Safety and Effectiveness

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

Submitter's Identification:	Bedfont Scientific Ltd 105 Laker Road Rochester, Kent, United Kingdom ME 1 3QX
Contact Person:	Mark Sandwell
Telephone: Fax:	011 44 8700 844050 011 44 8700 844051
Date of Summary:	March 30, 2007
Device Name:	EC50 ToxCo +
Classification Name:	Analyzer, Gas, Carbon Monoxide, Gaseous-Phase
Product Code:	CCJ
Product Class:	II
Code of Federal Regulation:	21 CFR 868.1430

Substantial Equivalence:

Manufacturer	Trade Name	510(k) Number
Bedfont Scientific	Smokerlyzer	K892841
Bedfont Scientific	piCO Smokerlyzer	K000962

7.2 Substantial Equivalence

The Bedfont EC50 ToxCO+, Bedfont piCO and Bedfont Smokerlyzer products are all part of the EC50 family, sharing similar electrochemical gas sensors for the detection of carbon monoxide. They share similar indications for use, accuracy, accessories and operating temperature ranges. All devices have similar power sources (Alkaline batteries) and meet general electrical standards IEC 60601-1. Bench testing has been carried out to ensure that the performance of the EC50 ToxCO+ is comparable with the predicate devices. Due to these similarities the ToxCO+ does not raise any new issues concerning safety and effectiveness.

1.1 Description

The EC50 ToxCO+ Breath Carbon Monoxide Monitor (*figure 1& 2*) is a handheld device, which provides a non-invasive means of determining Carbon Monoxide (CO) poisoning and Carboxyhaemoglobin (COHb) when blood testing is not available. The EC50 ToxCO+ Breath Carbon Monoxide Monitor is also ideal for use during triage to ensure suspected cases of CO poisoning are not missed.

The EC50 ToxCO+ Breath Carbon Monoxide Monitor is a microprocessor-controlled device powered by 2 AA batteries with an Alphanumerice LCD display housed in a sturdy ABS case with a synthetic rubber boot. The EC50 ToxCO+ Breath Carbon Monoxide Monitor is designed to have an operating temperature between 0-30° C, operating humidity 10-95% non-condensing and has storage temperature requirements of 0-30° C. The sensor sensitivity is 1 pmm, has a warm up time of <10 seconds-90% FSD, an accuracy of ±5% of reading, a concentration range of 0-50% COHb/0-500ppm CO and an H2 Cross Interference of <40% @ 20° C. The sensor operating life is 2-3 years with a company warranty of 6 months and requires calibrations at 6-month intervals.

The EC50 ToxCO+ Breath Carbon Monoxide Monitor is an easy to use handheld device (*figure 3*) that has three clearly marked buttons:

- ON button,
- CAL calibration button
- RECALL button

1.0 Indications for Use:

The EC50 ToxCO+ Breath Carbon Monoxide Monitor and accessories are used by healthcare professionals to determine levels of Carbon Monoxide (CO) poisoning.

1.2 Standards Met

The EC50 ToxCO+ Breath Carbon Monoxide Monitor has met IEC 60601-1 Electrical Safety for General Electrical Safety Standard and IEC 60601-1-2 Electromagnetic Compatibility – requirements and test. The mouthpiece used for the EC50 ToxCO+ Breath Carbon Monoxide Monitor is the same as the mouthpieces used for Bedfont EC50 Smokerlyzer Carbon Monoxide Monitor K892841 and Bedfont PICO Smokerlyzer Model EC-50 K000962 satisfying the ISO 10993 requirements. The facemasks used are commercially available for medical use and meet the requirements of ISO 10993.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2008

Bedfont Scientific Limited
C/O Mr. Daniel W. Lehtonen
Responsible Third Party Official
Intertek Testing Services NA, Incorporated
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

Re: K070259
Trade/Device Name: EC50 ToxCO+ Breath Carbon Monoxide Monitor
Regulation Number: 21 CFR 868.1430
Regulation Name: Carbon Monoxide Gas Analyzer
Regulatory Class: II
Product Code: CCJ
Dated: February 7, 2008
Received: February 8, 2008

Dear Mr. Lehtonen:

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.

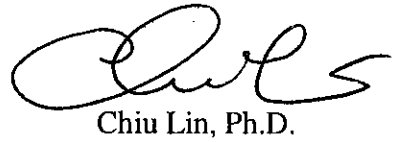
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 (240) 276-0120. 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/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: EC50 ToxCO+ Breath Carbon Monoxide Monitor

Indications For Use:

The EC50 ToxCO+ Breath Carbon Monoxide Monitor and accessories are used by healthcare professionals to determine levels of Carbon Monoxide (CO) poisoning.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

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