K062149

MAY 31 2007

PREMARKET NOTIFICATION [510(k)] SUMMARY

Date: July 19, 2006

1. **Submitter:**
   International Business Strategies, LLC
   1667A Marsh Harbor Lane
   Mount Pleasant, SC 29464

2. **Establishment Registration #:**
   3005159777

3. **Contact Person:**
   William H. Roettger
   Managing Member

4. **Contact Information:**
   Telephone: 843.224.0553
   Facsimile: 843.202.8915
   Email: bill@ibs-usa.com

5. **Proprietary Device Name:**
   SpO2 Sensor FS and PS "silc-touch" Series
   SpO2 Sensor FC, FP and Y Series
   (accessory to pulse oximeter)

6. **Classification Name:**
   Oximeter (DQA 870.2700)

7. **Common Name:**
   SpO2 Sensor (accessory to Pulse Oximeter)

8. **Manufacturer:**
   IT Dr. Gambert GmbH
   Hinter dem Chor 21
   23966 Wismar
   Germany

9. **Establishment Registration #:**
   9613449

10. **Contact Person:**
    Rainer Boettcher
    Business Development Manager

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11. Contact Information:

Telephone: +49 3841 22 00 50
Facsimile: +49 3841 22 00 522
Email: rboettcher@it-wismar.de

12. Predicate Devices:

K011518 Beta Biomed Services, Inc.

13. Intended Use:

IT Dr. Gambert's reusable SpO2 sensors are intended to non-invasively measure the pulse frequency and functional oxygen saturation of arterial hemoglobin (SpO2) when used in conjunction with various medical pulse oximeters. The sensors are to be used in accordance with the recommendations and specifications of the oximeter manufacturer.

14. Method of Operation:

IT Dr. Gambert's SpO2 Sensors operate on the principle of light absorption emitted through human tissue, e.g. through the index finger. The sensors use two light emitting diodes, one red and one infrared as light sources, and a photodiode to receive the light passing through the tissue. The photodiode converts the measurable light to an electrical current which is read on the measuring instrument as oxygen saturation. The saturation value is defined by the percentage ratio of the oxygenated hemoglobin (HbO2) compared to the total hemoglobin.

$$SpO2 = HbO2 / (Hb + HbO2)$$

All IT Dr. Gambert SpO2 sensors, and all predicate devices operate on the same principle described above and are substantially equivalent.

15.0 Performance Comparison at constant Temperature, Pressure and Humidity:

15.1 Re-usable SpO_2 Sensors

Product	**Beta Biomed K011518**	**IT Dr. Gambert**					
		FC	**FP**	**FS**	**PS**	**CA**	**CE**
Measurement Technique	Dual wavelength	same	same	same	same	same	same
Cable Length	4 ft / 10 ft	same	same	same	same	same	same
Measurement Range	0 - 100% SpO_2	same	same	same	same	same	same
Pulse Range (beats per minute)	20 - 250 bpm	same	same	same	same	same	same
Accuracy (70 – 100%)	± 2 digits	same	same	same	same	same	same
Accuracy (Pulse rate)	± 3 digits	same	same	same	same	same	same
Operating Temperature	5 – 45°C	same	same	same	same	same	same

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Sensor types differ only in body shape and connection. They are otherwise identical and are treated the same for technical comparison.

16. Description:

IT Dr. Gambert's reusable SpO2 sensors are produced in several configurations as after market replacements for use with a wide variety of commercially available pulse oximeters. They are substantially equivalent (identical) to the listed predicate devices and all other SpO2 sensors currently cleared for marketing in the United States.

17. Recognized Quality Assurance Standards:

IT Dr. Gambert's SpO2 sensors are classified as Class IIa devices according to EC Council Directive 93/42/EEC, Annex I. All IT Dr. Gambert products display CE Mark 0124.

18. Conclusion:

IT Dr. Gambert's re-usable SpO2 sensors are substantially equivalent to the listed predicate devices in terms of materials, performance, construction and operating principles. They have been tested, and according to EC-Council Directive 93/42/EEC, have been found to be safe and effective when used in conjunction with manufacturer's recommendations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 31 2007

Mr. Bill Roettger
Managing Member
International Business Strategies, LLC
1667A Marsh Harbor Lane
Mount Pleasant, South Carolina 29464

Re: K062149
Trade/Device Name: SpO2 Sensor FS and PS "Silc-Touch" Series; SpO2 Sensor FC, FP, and Y Series
Regulation Number: 870. 2700
Regulation Name: Oximeter
Regulatory Class: II
Product Code: DQA
Dated: May 3, 2007
Received: May 4, 2007

Dear Mr. Roettger:

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 K062149:

Device Name: SpO2 Sensors, the FS and PS "silc touch" Series and FC, FP and Y Series

Indications for Use:

IT Dr. Gambert's reusable medical SpO2 sensors, the FS and PS "silc touch" Series and FC, FP and Y Series, are intended to non-invasively measure the pulse frequency and functional oxygen saturation of arterial hemoglobin (SpO2) when used in conjunction with the BCI Advisor, Datex Ohmeda TuffSat, HP Philips M3, Nellcor NPB-40 and Novametrix 512 pulse oximeters. The sensors are to be used in accordance with the recommendations and specifications of the oximeter manufacturer.

Prescription Use ___X___ 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)

...sion Sign-Off)
...vision of Anesthesiology, General Hospital,
...fection Control, Dental Devices

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