JAN 12 2006

510(k) Number K052176 Date _____

Flowhandy ZAN100 USB
510(k) Summary

Submitter

Company: ZAN Messgeräte GmbH
Schlimpfhofer Strasse 14, D-97723 Oberthulba, Germany
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Contact: Jim Lewis
Ferraris Respiratory Inc, 908 Main Street, Louisville CO 80027, USA
Tel 303 666 5555, Fax 303 666 5588

Prepared: August 2005

Device Name

Trade: Flowhandy ZAN100 USB
Common: Spirometer
Classification: Diagnostic spirometer, 21 CFR 868.1840; Class II
Product code: 73-BZG

Predicate Devices

Trade Name: MasterScreen Pneumo
510(k) Number: K933839
Manufacturer: Erich Jaeger Gmbh

Device Description

The Flowhandy ZAN100 USB is a pneumotachometer spirometry system. The system comprises a Windows personal computer (sold separately) for data collection, analysis, storage, and display; proprietary Betterflow ZAN100 USB software program for the PC; and a Flowhandy hand-held pneumotach with reusable variable-orifice core, differential pneumatic pressure sensor, and USB interface. An optional computer-controlled shutter may be added to the air passageway to interrupt flow to allow pressure measurements using the on-board pressure sensor.

The ZAN100 measures the pressure drop across the known orifice to indicate the rate of breath flow both in and out of the air passageway. Knowing the flow rate of air from a subject allows the calculation of the most recognized spirometric values for the subject. Closing off the passageway with the optional shutter enables the pressure sensor to take important pressure measurements for the subject's breathing as well.

Indications for Use

The Flowhandy ZAN100 USB is an open, personal-computer-based spirometry system with optional shutter for measuring and analyzing breath flow, volume, and pressure in adult and pediatric subjects for use by pulmonologists, allergists, general practitioners, and occupational-medicine practitioners in lung-function diagnosis.

Summary of Technological Characteristics

The Flowhandy uses the pressure difference in the air stream across a variable-orifice diaphragm to measure a subject's airflow rate (pneumotachometry) throughout established breathing maneuvers to provide spirometric analysis. The instantaneous flow rate values are acquired on a personal computer, where the data is analyzed, stored, and displayed. The optional shutter is a solenoid-activated valve for interrupting airflow.

Technical Specifications

- Operating temperature range: 10 to 40 °C
- Operating humidity: 20 to 90%, non-condensing
- Storage temperature: 0 to 40 °C
- Storage humidity: 10 to 90%, non-condensing
- Material: POM (polyoxymethylene)
- Enclosure rating: IPX1
- Type of applied part: BF (subject floating)

Flow sensing

- Measuring principle: Pressure difference with variable diaphragm (pneumotachometry)
- Dimensions: 100x90x45 mm
- Weight: 250 g
- Power supply: 5 VDC, 0.2 W_{max} (powered from USB port)
- Pressure transducer: Semiconductor; 0 to 1.4 kPa; 0.1% accuracy
- Volume resolution: <5 ml
- Flow resolution: <1 ml/s
- Range: 0 to 15 l/s, bi-directional
- Max linearity error (corrected): 2.5%
- Flow resistance: <0.03 kPa/l/s
- Effective dead space: <50 ml

Shutter valve for mouth/nasal pressure reading

- Dimensions: 180x50x80 mm
- Weight: 420 g
- Additional dead space: <30 ml
- Mouth/Nasal pressure transducer: Semiconductor; 0 to 7 kPa; 0.2% accuracy
- Power supply: 5 VDC, 0.5 W_{max} (powered from USB port)

Summary of Non-Clinical Performance Data

Safety

The Flowhandy was examined and bench tested by third-party examiners to demonstrate conformance to three recognized international consensus standards for safety of medical electrical equipment: EN 60601-1 for general medical-device safety, EN 60601-1-1 for medical electrical safety, and EN 60601-1-2 for electromagnetic compatibility.

Effectiveness

In-house and third-party testing demonstrate that Flowhandy measurement performance meets or exceeded published American Thoracic Society requirements and the claimed performance requirements under stated and anticipated operating conditions.

Summary of Clinical Performance Data

CE marking and years of successful operation in Europe demonstrate that patients and clinicians can safely and effectively use the Flowhandy under actual-use conditions and that the users guide, product physical design, and other human-factor characteristics of the Flowhandy system are appropriate for the product's intended use.

Equivalence to Predicate Devices

The Flowhandy design uses the same technologies and design principles as its predicate devices. The system is substantially equivalent to Jaeger's MasterScreen Pneumo: using the same measurement principles; similar construction, material, and energy source; and meeting the same performance characteristics and intended uses.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 12 2006

Zan Messgerate GmbH
C/O Mr. Jim Lewis
Ferraris Respiratory, Incorporated
908 Main Street
Louisville, Colorado 80027

Re: K052176
Trade/Device Name: Flowhandy ZAN100 USB
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: December 27, 2005
Received: December 28, 2005

Dear Mr. Lewis:

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.

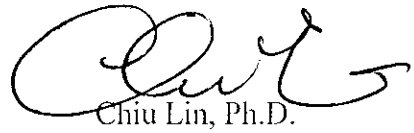
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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: Flowhandy ZAN100 USB

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

[signature]

[illegible], General Hospital, [illegible] Devices

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