Technology in Practice™

510(k) Summary of Safety and Effectiveness K120880

Date: 3/15/12

APR 19 2012

Submitter:
National Biomedical LLC, dba QRS Diagnostic
Street Address: 6901 E. Fish Lake Road #188
City: Maple Grove
State: MN
Zip Code: 55369
Telephone: 763-559-8492
Facsimile: 763-559-2961

Contact: Mary Kay Jensen
Phone: 763-515-5323
Facsimile: 763-559-2961
e-mail: mkjensen@qrsdiagnostic.com

Device Name:
Trade Name: Orbit Spirometer
Common Name: Spirometer
Classification Name: Spirometer, Diagnostic
Classification: Listed as Class II
Panel Code: BZG
Regulation Number: 868.1840

Identification of Legally Marketed (Unmodified) Device (Predicate Device):

Name of Predicate	Manufacturer	Use	510K)	Date Cleared
SpiroCard	QRS Diagnostic	Spirometer	K973138	10/8/1998

Device Description:
The QRS Orbit product model Z-7000-0101 consisting of a spirometer, pressure tube, disposable pneumotachometer, Office Medic Software and a host computer is a compact and versatile personal computer (PC) based pulmonary function analyzer (spirometer). The product measures a patient's expiratory and inspiratory airflow, analyzes the data with print options that includes the measured and predicted values and flow vs. volume or volume vs. time graphs.

The Orbit spirometer includes the following components:

- Spirometer
- Spirometer Pressure Tube
- Disposable pneumotachometer (mouthpiece)
- Office Medic Software

- Host PC (User Provided)

Indications for Use

- Device Functionality: Spirometry
- Primary Spirometric Parameters: FVC, MVV, SVC and FEF
- Patient Population: Male/Female, Pediatric to Adult
- Environment of Use: Hospital, Clinic and Home Use under trained professional supervision (Prescription Use)

The QRS Diagnostic Orbit Spirometer is intended for the acquisition, analysis, display and print of measurements and waveforms of pulmonary function for the purpose of assisting clinicians in the diagnosis of various pulmonary function diseases and/or treatment regimens.

Technological Comparison to (Unmodified) Predicate Device:

The following summary table of comparisons compares the Modified Orbit Device to the Previously Cleared SpiroCard Device:

#	Area	Modified Device (Orbit)	Previously Cleared Device (SpiroCard)	Same	Different
Indications for Use					
1	Patient Population	Male/Female Pediatric to Adult	Male/Female Pediatric to Adult	X	
2	Environment of Use	Hospital, Clinic, Home Use	Hospital, Clinic, Home Use	X	
Fundamental Scientific Technology					
3	Interpretation Algorithm	Interpretation Algorithm functions per specification	Interpretation Algorithm functions per specification	X	
4	Device Components	• Spirometer (PCB, Pressure Transducer and Enclosure) • Plastic Mouthpiece • Pressure Tube • Computer with Windows OS • Software	• Spirometer (PCB, Pressure Transducer and Enclosure) • Plastic Mouthpiece • Pressure Tube • Computer with Windows OS • Software	X	
Contraindications					
5	Contraindications	No contraindications	No contraindications	X	
Sterility/Expiration Dating					
6	N/A	N/A	N/A	X	
Energy Type					

#	Area	Modified Device (Orbit)	Previously Cleared Device (SpiroCard)	Same	Different
7	Energy Type	AC or Battery Based upon computer utilized	AC or Battery Based upon computer utilized	X	
Environmental Specifications					
8	Temperature	-15 to 50° C	-15 to 50° C	X	
9	Relative Humidity	90% Maximum (non-condensing)	90% Maximum (non-condensing)	X	
10	Atmospheric Pressure	700 to 1060 hPa	700 to 1060 hPa	X	
Operating Specifications					
11	Temperature	15 to 40° C	15 to 40° C	X	
12	Relative Humidity	10 to 90% (non-condensing)	10 to 90% (non-condensing)	X	
13	Atmospheric Pressure	700 to 1060 hPa	700 to 1060 hPa	X	
Performance Standards					
14	American Thoracic Society (ATS/ERS) 2005 Standard	Complies	Complies	X	
15	British Thoracic Society (BTS) Standard	Complies	Complies	X	
16	National Institute for Health and Clinical Excellence (NICE) Guidelines	Complies	Complies	X	
17	Safety - IEC/EN 60601-1	Complies	Complies	X	
18	Electromagnetic Compatibility (EMC) - IEC/EN 60601-1-2	Complies	Complies	X	
Hardware					
19	Enclosure Dimensions	127mm (L) x 102mm (W) x 51mm (H)	140(L) mm x 53 mm (W) x 16 mm (H)		X
20	Enclosure Material	Metalized LCP	ABS and Polycarbonate		X
21	Pressure Transducer	New-Improved Performance- +/- 10 inches of water	+/- 10 inches of water		X
22	Analog front-end	A more precise instrumentation amplifier was used with active filtering. Pressure: +/- 6.2 inches of water Gain=96 v/v Bandwidth= 16 Hz	Pressure: +/- 6.2 inches of water Gain=127 v/v Bandwidth=16 Hz		X

#	Area	Modified Device (Orbit)	Previously Cleared Device (SpiroCard)	Same	Different
23	A/D Converter	16-bit resolution Sampling rate = 125 Hz	16-bit resolution Sampling Rate= 100 Hz		X
24	Power Supply	New-Designed for USB provided power	Designed for PCMCIA power		X
25	Interface Connection Type	USB	PCMCIA		X
Software/Firmware					
26	Micro Processor	Updated	Existing		X
27	Sample Rate	125 samples/second	100 samples/second		X
28	Software Drivers	USB Connection Driver	PCMCIA/Serial Connection Driver		X
29	Spirometry Calculation DLL	Add interface for USB Spirometer	No interface for USB Spirometer		X

Summary of Performance Testing:
The QRS Diagnostic Orbit Spirometer has been tested or found otherwise to comply with applicable sections of the following standards:

- American Thoracic Society (ATS/ERS) 2005 Standard
- Safety - IEC/EN 60601-1 3rd Ed., Medical electrical equipment – Part 1: General requirements for basic safety and essential performance
- Electromagnetic Compatibility (EMC) - IEC/EN 60601-1-2 3rd Ed., Medical Electrical Equipment - Part 1-2: General requirements for safety - collateral standard: Electromagnetic compatibility - Requirements and Test.

Conclusions:
The results of the tests discussed above, indicate that the modified QRS Diagnostic Orbit device is as safe, as effective, and performs as well as or better than the non-modified device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002.

Ms. Mary Kay Jensen
Quality Assurance/Regulatory Affairs Consultant
National Biomedical LLC, dba QRS Diagnostic
6901 E. Fish Lake Road #188
Maple Grove, Minnesota 55369

APR 19 2012

Re: K120880
Trade/Device Name: Orbit Spirometer
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG
Dated: March 19, 2012
Received: March 23, 2012

Dear Ms. Jensen:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

Anthony D. Watson, B.S., M.S., M.B.A.
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): *To be determined*

Device Name: Orbit Spirometer

Indications for Use:

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Prescription Use _X___ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K120860