



Food and Drug Administration
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October 20, 2016

Fim Medical
% Daniel Kamm
Principal Engineer
Kamm & Associates
8870 Ravello Ct
Naples, Florida 34114

Re: K161676

Trade/Device Name: Q13 SPIROLYSER®
Regulation Number: 21 CFR 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: Class II
Product Code: BZG
Dated: September 14, 2016
Received: September 19, 2016

Dear Daniel Kamm:

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 contact the Division of Industry and Consumer Education 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>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Tina Kiang, Ph.D.
Acting Director
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Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K161676

Device Name

Q13 SPIROLYSER®

Indications for Use (Describe)

Intended to perform spirometry in hospital and clinical environments, for adult patients and pediatric patients aged 6 years and above.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(K) Summary, 510(k) K161676

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Contact: Marie-Ange Derei, President

Date Prepared: October 20, 2016

1. **Identification of the Device:**
Proprietary-Trade Name: Q13 SPIROLYSER®
Classification Name: Spirometer
Common/Usual Name: Spirometer
Device Class: II per regulation 868.1840 Product Code BZG
2. **Equivalent legally marketed device: K010761, SPIROLYSER SPL-50, FIM Medical**
3. **Indications for Use: Intended to perform spirometry in hospital and clinical environments, for adult patients and pediatric patients aged 6 years and above.**
4. **Description of the Device:** The SPIROLYSER® Q13 is an electronic spirometer operating on a PC, for the exploration of respiratory function. The spirometer is composed of a single-use sensor that propels the air (FLEISCH principle) and obtains a difference in pressure. Definition of Fleisch type pneumotachograph: A pneumotachograph that measures flow in terms of the proportional pressure drop across a resistance consisting of numerous capillary tubes in parallel. The SPIROWIN® EXPERT software acquires samples sent by the spirometer and determines a flow and a volume so as to display the curves and deduce results. The SPIROLYSER® Q13 spirometer is a portable device. In normal use, the patient holds it by the handle, placing the single-use sensor in the mouth. The SPIROLYSER® Q13 is directly powered by the computer USB port via its USB lead. The SPIROWIN® EXPERT software (on the attached PC) calculates, displays and stores data to help the practitioner in the exploration of a patient's respiratory function. The SPIROLYSER® Q13 should only be used by health professionals (doctor, lung specialist, allergist ...). Results should only be interpreted by health professionals having undergone pneumology training.
5. **Safety and Effectiveness, comparison to predicate device.** This device has the same **indications for use** and very similar technological characteristics as the predicate device.
6. **Substantial Equivalence Chart: Please see the next page.**

7. Substantial Equivalence Chart

	Spirolyser SPL-50 K010761 (Predicate)	Q13 [®] Spirolyser [®]	Assessment of Differences and why device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness
Device Type	Portable	Portable	Same
Indications for Use	Intended to perform spirometry and may be used in hospitals and medical offices or at other locations including homes.	Intended to perform spirometry in hospital and clinical environments, for adult patients and pediatric patients aged 6 years and above.	Slightly revised wording, no real difference. Patient population now specified.
Weight	Out of case 1 Kg with case 2.5 Kg	250g without PC	Not relevant to safety/ effectiveness
Power Supply	110/220 VAC ~ output 12 volts DC	5V DC via USB	DC, same.
Sensor	Fleisch type sensor pneumotachograph Multiple Use with filter accessory Ergofilter™ SP1 Accessory (K050424)	Fleisch type sensor pneumotachograph Single USE	Single use is safer, lowers the possibility of cross-contamination
Measurement Range	- 9 l/s to + 14 l/s	-14 L/s to +14 L/s	New device is better
Volumes	0 to 10 liters	0 to 10 liters	Same
Accuracy	+/- 3%	< ±3%	Same
Resolution	12 bits	15 bits	New device is better
Display	Graphic LCD128 x 64 pixels	No, 1024x768 min on PC	New device is better
Printer	58 mm thermal	PC Connected, User's choice	New device is better
Tests	Slow Vital Capacity, Forced Vital Capacity, Maximum Voluntary Ventilation, Pre/Post-Medication	Slow Vital Capacity, Forced Vital Capacity, Maximum Voluntary Ventilation, Pre/Post-Medication	SAME
Curves	Flow/volume loop, volume/time, pre/post-medication, predictive curves	Flow/volume loop, volume/time, pre/post-medication, predictive curves	SAME
Correction	BTPS, temperature, Hygrometry, Atmos. pressure.	BTPS, temperature, Hygrometry, Atmos. pressure.	SAME.
Predictive norms	Knudson, Eccs (SECCA), ITS (Crapo), Polgar	Knudson, Eccs (SECCA), ITS (Crapo), Polgar, NHANES III	NHANES III added for Canada

	Spirolyser SPL-50 K010761 (Predicate)	Q13 [®] Spirolyser [®]	Assessment of Differences and why device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness
Interpretation	Perdrix - CHU Grenoble	Perdrix - CHU Grenoble	SAME
Other	Auto date, 150 tests memorized, transfer to PC, calibration, management of calibrations	Auto date, essentially unlimited tests memorized, calibration, management of calibrations	Use of the attached laptop allows for unlimited tests to be memorized which we see as advantageous.
Reference standards:	IEC 60601-1, IEC 60601-1-2	IEC 60601-1, IEC 60601-1-2, ATS 2005 (American Thoracic Society)	ATS compliance enhances effectiveness.
Photo			The larger display screen is easier to read. The use of a laptop permits the user to use their local printer instead of the small format thermal paper printer. Better for archiving.
PATIENT CONTACT MATERIALS Biocompatibility	ABS plastic handle (shown above) and “Ergofilter” (K050424) (contacts patient’s mouth/mucosa) Moplen HP648N (6331NW) Antistatic and Nucleated Polypropylene Homopolymer Resin (safe for food contact) Nose clip	Patient Contact items: Single use Qflow [®] sensor made of polypropylene contacts patient’s mouth/mucosa. Patient holds the ABS plastic handle (shown above). A foam nose clip is worn by the patient. ISO 10993 testing conducted on the Qflow [®] sensor, the handle, and the Nose clip	Single use mouth contact piece reduces the possibility of cross contamination.
Operating Temperature	17°C - 37°C	17°C - 37°C	SAME
Storage Temperature	0°C - 50°C	0°C - 50°C	SAME
Hygrometry	75% max.	75% max.	SAME

	Spirolyser SPL-50 K010761 (Predicate)	Q13 [®] Spirolyser [®]	Assessment of Differences and why device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness
Operating Altitude	< 2000m	< 2000m	SAME
Supplied Accessories	Transport case Mains supply and battery 1 nose-clip 2 rolls of paper 1 filter	1 computer software (Spirowin [®] Expert) 1 calibration certificate 1 software license 2 single use Qflow [®] sensors Optional, recommended: Single Use Nose Clip	No substantial difference in Safety/ Effectiveness but single use sensor reduces cross-contamination risk.
Option	Transfer to Computer	Transfer to Computer is standard, required.	No material difference in Safety/ Effectiveness

The technological characteristics, including design, materials, composition, and energy source, are substantially the same, so there are no issues impacting safety and effectiveness, as detailed in the right hand column in the table above.

8. **Summary of non-clinical testing:** Biocompatibility of the mouthpiece, handle, and the nose clip was evaluated according to FDA recommendations and ISO 10993 standards for cytotoxicity, irritation, and sensitization (ISO 10993-5 (2009) and ISO 10993-10 (2010)). Software validation and risk analysis was performed. Electrical safety (IEC 60601-1:2005) and EMC compatibility (IEC 60601-1-2:2007) testing was successfully performed. Bench testing also included Compliance with ATS 2005 Spirometry Testing Recommendations. Using its flow/volume Pulmonary Waveform Generator the FIM MEDICAL has carried out all essential requirements recommended by the American Thoracic Society (ATS 2005). The measurements were performed several times in order to check repeatability, as well as the performance of the Spirolyser[®] Q13 spirometer. All the results obtained are below the tolerated maximum errors on all the FT and PW curves tested, in both positive and negative flows. All test results were satisfactory.
9. **Summary of clinical testing:** Not required. Bench testing was sufficient to establish the performance characteristics as being safe and effective.
10. **Conclusion:** The Q13[®] Spirolyser[®] is as safe and as effective as the predicate device. It has insignificant technological differences, and has essentially identical indications for use, thus rendering it substantially equivalent to the predicate device. The small differences do not impact safety or effectiveness..