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.
Clinical Deputy Director
DAGRID/ODE/CDRH
For

Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.*

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRASStaff@fda.hhs.gov

“An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number.”
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.
### Substantial Equivalence Chart

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Portable</th>
<th>Portable</th>
<th>Same</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Indications for Use</strong></td>
<td>Intended to perform spirometry and may be used in hospitals and medical offices or at other locations including homes.</td>
<td>Intended to perform spirometry in hospital and clinical environments, for adult patients and pediatric patients aged 6 years and above.</td>
<td>Slightly revised wording, no real difference. Patient population now specified.</td>
</tr>
<tr>
<td><strong>Weight</strong></td>
<td>Out of case 1 Kg with case 2.5 Kg</td>
<td>250g without PC</td>
<td>Not relevant to safety/effectiveness</td>
</tr>
<tr>
<td><strong>Power Supply</strong></td>
<td>110/220 VAC ~ output 12 volts DC</td>
<td>5V DC via USB</td>
<td>DC, same.</td>
</tr>
<tr>
<td><strong>Sensor</strong></td>
<td>Fleisch type sensor pneumotachograph Multiple Use with filter accessory Ergofilter™ SP1 Accessory (K050424)</td>
<td>Fleisch type sensor pneumotachograph Single USE</td>
<td>Single use is safer, lowers the possibility of cross-contamination</td>
</tr>
<tr>
<td><strong>Measurement Range</strong></td>
<td>-9 l/s to +14 l/s</td>
<td>-14 L/s to +14 L/s</td>
<td>New device is better</td>
</tr>
<tr>
<td><strong>Volumes</strong></td>
<td>0 to 10 liters</td>
<td>0 to 10 liters</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Accuracy</strong></td>
<td>+/- 3%</td>
<td>&lt; ±3%</td>
<td>Same</td>
</tr>
<tr>
<td><strong>Resolution</strong></td>
<td>12 bits</td>
<td>15 bits</td>
<td>New device is better</td>
</tr>
<tr>
<td><strong>Display</strong></td>
<td>Graphic LCD128 x 64 pixels</td>
<td>No, 1024x768 min on PC</td>
<td>New device is better</td>
</tr>
<tr>
<td><strong>Printer</strong></td>
<td>58 mm thermal</td>
<td>PC Connected, User’s choice</td>
<td>New device is better</td>
</tr>
<tr>
<td><strong>Curves</strong></td>
<td>Flow/volume loop, volume/time, pre/post-medication, predictive curves</td>
<td>Flow/volume loop, volume/time, pre/post-medication, predictive curves</td>
<td>SAME</td>
</tr>
<tr>
<td><strong>Correction</strong></td>
<td>BTPS, temperature, Hygrometry, Atmos. pressure.</td>
<td>BTPS, temperature, Hygrometry, Atmos. pressure.</td>
<td>SAME.</td>
</tr>
<tr>
<td><strong>Predictive norms</strong></td>
<td>Knudson, Eccs (SECCA), ITS (Crapo), Polgar</td>
<td>Knudson, Eccs (SECCA), ITS (Crapo), Polgar, NHANES III</td>
<td>NHANES III added for Canada</td>
</tr>
<tr>
<td><strong>Interpretation</strong></td>
<td>Perdrix - CHU Grenoble</td>
<td>Perdrix - CHU Grenoble</td>
<td>Assessment of Differences and why device is as safe and effective as the predicate and does not raise different questions of safety and effectiveness</td>
</tr>
<tr>
<td>-----------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td><strong>Other</strong></td>
<td>Auto date, 150 tests memorized, transfer to PC, calibration, management of calibrations</td>
<td>Auto date, essentially unlimited tests memorized, calibration, management of calibrations</td>
<td>Use of the attached laptop allows for unlimited tests to be memorized which we see as advantageous.</td>
</tr>
<tr>
<td><strong>Photo</strong></td>
<td><img src="image1.png" alt="Photo" /></td>
<td><img src="image2.png" alt="Photo" /></td>
<td>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.</td>
</tr>
<tr>
<td><strong>PATIENT CONTACT MATERIALS</strong></td>
<td>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</td>
<td>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</td>
<td>Single use mouth contact piece reduces the possibility of cross contamination.</td>
</tr>
<tr>
<td><strong>Operating Temperature</strong></td>
<td>17°C - 37°C</td>
<td>17°C - 37°C</td>
<td>SAME</td>
</tr>
<tr>
<td><strong>Storage Temperature</strong></td>
<td>0°C - 50°C</td>
<td>0°C - 50°C</td>
<td>SAME</td>
</tr>
<tr>
<td><strong>Hygrometry</strong></td>
<td>75% max.</td>
<td>75% max.</td>
<td>SAME</td>
</tr>
</tbody>
</table>
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 were 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 of effectiveness.