ATTACHMENT A1

MAR 2 1 2003

Section 2: h) 510(k) Summary

K020102

IQTeQ Spirometer 2001

1. **Applicant:**
   Choice Decisions 86 (PTY) LTD trading as IQTeQ Development
   The Penthouse,
   Jaga House,
   61 Wale Street
   Cape Town 8001

   Contact person: Ray Wright, Director, Research and Development

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   Date prepared: January 6, 2002

2. **Device name:**
   Proprietary name: IQTeQ Spirometer 2001
   Common/Usual name: Diagnostic Spirometer
   Classification Name: Diagnostic Spirometer
   Classification Panel: Anesthesiology
   Classification Code: 73BZG
   Classification: Class II, according to 21 CFR, 868.1840

3. **Predicate Devices/ Substantial Equivalence:**
   The IQTeQ Spirometer is substantially equivalent to:

   3.1: Serial Flow or also known as the PCFlow+
   K900673
   Manufactured Spirometrics Medical Equipment Company

   3.2 Brentwood IQMark tm Digital Spirometer
   K002499
   Manufactured by Brentwood Medical Technology Corporation

4. Device Description:
The IQTeQ Spirometer2001 is a handheld spirometer that connects to a Personal Computer (PC) via a Universal Serial Bus (USB) port cable connection. Windows based software on the PC runs the diagnostic spirometer application.

The device consists of a plastic handle which houses the amplified pressure transducer, analog to digital conversion, USB microcontroller and connection to the USB cable. The electronic component is screened and connects to the USB cable screen. The entire electronic component is sealed in epoxy (Eli-Cast FR 453) and permanently fixed into the handle with epoxy. The electronics in the handle is powered by the 0 and 5volt power supply, which is provided with all USB ports. The top of the handle has a circular tube for connection to the flow tube, which is inserted into the handle tube.

The flow tube, which includes a laminar flow air resistance element, is inserted into the handle tube. Porting of the flow tube and the handle tube allows air pressure to connect to the pressure transducer in the handle. Two 'O' rings maintain an airtight seal between the tubes. The flow tube includes an inert ceramic (CORDIERITE) laminar flow air resistance element.

The patient is connected by mouth to a bacterial filter, which is fitted to the flow tube. The patient breathes as instructed through the flow tube. The pressure transducer in the handle continuously transmits the differential pressure in the flow tube to the analog to digital converter. The digitized 12 bit data is sent to the PC via the USB port at 335, 12bit samples per second. The IQTeQ application software which requires Windows 98 SE or later calculates the flow and integrates flow to calculate volume. The flows are calculated from the 12 bit data by applying the calibration polynomial algorithm. Therefor all flow and volume data is calculated in real time for the flow-volume measurements which includes: Peak Flow, Forced Vital Capacity, Forced Expiratory Flows Forced Inspiratory Vital Capacity as well as MVV and SVC.

The spirometer technician/operator uses the software on the PC to conduct the tests. The software includes a number of screens and 'buttons' that help to logically perform the tests in the correct order. The tests can be saved to the hard drive, printed (reports) and recalled. There are various parameters that are displayed to assist the technician in quality control of the test procedure as is requested by the ATS 1994 update document.

The system has a calibration procedure that requires 6 varying strokes from a 3 liter syringe.

5. The IQTeQ Spirometer is indicated for use by Adult/Pediatric, Male/Female, to monitor, measure and evaluate pulmonary function parameters the in hospitals, clinics, physicians offices, industrial health screening and homes (as prescribed by a physician) of the following:

Forced Flow/Volume measurements, Forced Flows, Slow Vital capacity, Forced Inspiratory Volumes and Flows, MVV.
To evaluate the presence, extent, progression, physiologic disturbance and course of therapy of lung disease.

6. Comparison to predicates:

The IQTeQ Spirometer is similar to the predicates in #3. The only significant difference is the method of communication to the PC. The predicate devices both connected by serial port. The IQTeQ Spirometer connects via the newly adopted Universal Serial Bus (USB) PC standard, which supercedes the serial port. The USB has a number of advantages over the serial port. The USB port supplies a 5 volts power supply. Devices that connect to the PC via USB are 'Plug n Play', devices which communicate at higher speeds and more reliably than the serial port. PC's do not come equipped with serial ports anymore and only USB ports are fitted. Apart from small software design layout differences and other minor differences in characteristics The IQTeQ Spirometer is substantially equivalent to the predicate devices and does not raise any new questions regarding safety or effectiveness.
As with the predicate devices, the IQTeQ Spirometer has been tested for compliance to the ATS1994 standards. The IQTeQ Spirometer also complies with the EN60601-1, IEC60601-1 electrical safety and emmision standards.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2003

Mr. Raymond E. Wright
Director Research & Development
IQTeQ Development
The Penthouse
Jaga House, 61 Wale Street
Cape Town, Western Cape 8001
SOUTH AFRICA

Re: K020102
Trade/Device Name: IQTeQ Spirometer
Regulation Number: 868.1840
Regulation Name: Diagnostic Spirometer
Regulatory Class: II
Product Code: BZG, BTY, BZC, BZM
Dated: January 26, 2003
Received: February 7, 2003

Dear Mr. Wright

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 (301) 594-4646 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/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim 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 STATEMENT

Device Name: IQTeQ Spirometer. **510(k) number: k020102**

Indications for use:

The IQTeQ Spirometer is intended for use as a prescription-use-only clinical diagnostic spirometer for pulmonary function evaluation and data management.

The IQTeQ Spirometer is for use in hospitals, clinics and physician/clinician offices by individuals that have received minimal instruction or training in the administration of spirometry tests. The IQTeQ Spirometer operates with an IBM or compatible computer using a USB port (Universal serial bus) connection and the PC's installed IQTeQ Spirometer Windows™ compatible software. Minimum PC and operating system requirements are specified in the IQTeQ Spirometer Manual.

The IQTeQ Spirometer is indicated for use with male/female adult patients and male/female pediatric patients to evaluate, access, describe, measure, or monitor:

1. Symptoms, signs, or abnormal laboratory tests
2. Effects of disease on pulmonary function
3. Individuals at risk for pulmonary disease
4. Preoperative risk
5. Post-surgical prognosis
6. Pre-treatment health status
7. Therapeutic interventions
8. The course of disease affecting lung function
9. Persons exposed to pollutants
10. Adverse reactions to drugs with known pulmonary toxicity
11. Rehabilitation programs
12. Risks as part of an insurance evaluation
13. Individuals for legal reasons
14. Epidemiological surveys
15. Derivation of reference equations

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K020102

Prescription Use ✓ OR Over-The-Counter USE ____
(Per 21 CFR 801.109)