K992163

JUL 13 1999

Attachment 4

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The assigned 510(k) number is:_____

A. Type of Submission: Special 510(k): Device Modification

B. Applicant's Name, Address, Contact Person and Date of Preparation

PDZ Europa Limited
Europa House, Electra Way
Crewe, Cheshire CW1 6ZA
United Kingdom

Note that the predicate device 510(k), K974322, was submitted under the name Europa Scientific Limited. Effective November 3, 1998, Europa Scientific Limited (Europa House, Electra Way, Crewe, Cheshire, UK) became **PDZ Europa Limited** at the same address. PDZ Europa Limited has assumed manufacturing operations and distribution rights for all Europa Scientific's products and services. The Device Establishment Registration Number, Owner/Operator number and Device Listing information has been transferred from Europa Scientific Limited to PDZ-Europa Limited.

Please direct any requests for information to:

Clive Workman
Chief Executive
PDZ Europa Limited
Europa House, Electra Way
Crewe, Cheshire CW1 6ZA
United Kingdom

Phone: +44-1270-589398
Fax: +44-1270-589412

This 510(k) was prepared June 12, 1999

C. Trade Name of the Device: ABCA Gas Isotope Ratio Mass Spectrometer System

D. Common Name of the Device: Gas Isotope Ratio Mass Spectrometer System

E. Classification

Product Code:	91DOP
Name, Class:	Mass Spectrometer, Clinical Use, Class 1
Reg. Number:	21CFR 862.2860

F. The Predicate Device

Trade Name: ABCA-NT Gas Isotope Ratio Mass Spectrometer System
510(k) number: K974322
510(k) clearance date: December 16, 1997

G. Description of the Device

The ABCA is an acronym for a configuration of modules intended for use in analysis ^{13}C and ^{18}O in CO_2 and ^{15}N in N_2 and N_2O gas samples. The ABCA System includes:

- The Europa 20-20 continuous flow IRMS
- A gas purification module (Gas Chromatograph)
- An autosampler
- An IBM (or compatible) personal computer for system control, data analysis and data storage

1. Principle of Operation

Gas samples for analysis are contained in tubes which may be either pre-evacuated or flushed with air or helium. Most commonly, pre-evacuated tubes such as Exetainers® or Vacutainers® are used and are placed in the holding rack of the autosampler of the System. During operation, the sample probe moves over each tube in turn and either aspirates an aliquot of sample or sweeps the entire gas sample from the sample tube to the gas purification module with purified helium. Prior to injection, the probe is purged with helium to rid it of any air.

The helium carrier gas plus sample gases pass through a solid desiccant to remove water vapor, then into a gas chromatographic (GC) column which separates sample gas components. When carbon dioxide is the species of interest, it is undesirable for nitrogen and oxygen to enter the Isotope Ratio Mass Spectrometer. To prevent this, a secondary helium flow moves into the IRMS module while oxygen and nitrogen are directed to waste by a Diverter Valve. As the CO_2 emerges from the column, the valves switch to direct the pure CO_2 into the IRMS with the secondary helium flow directed to waste.

Once in the IRMS, the neutral molecules, e.g., $^{12}CO_2$ and $^{13}CO_2$, are ionized in the 'Source' producing positively charged ions, e.g., $^{13}CO_2^+$ and $^{12}CO_2^+$. The charged molecules are then given a precise amount of energy by an electric field and directed into a magnetic field where they follow curved paths dependent on the mass to charge ratio. The separated 'beams' of molecules are focused on *three* different Faraday 'bucket' collectors, thus generating independent electrical currents corresponding to masses 44, 45, and 46 amu. The ratio of currents generated at the 45 and 44 amu collectors corresponds to the ratio of $^{13}CO_2$ to $^{12}CO_2$ in the original gas sample. The current generated at the 46 amu collector corresponds to the $^{12}C^{16}O^{18}O^+$ ion and is used to correct for contributions of $^{12}C^{16}O^{17}O^+$ to the 45 amu current using the Craig correction since the $^{17}O/^{18}O$ ratio is constant.

2. Calibration

The system is calibrated with reference gas of known isotopic composition. The reference gas may be contained in sample tubes in the autosampler or may be introduced directly from a gas cylinder.

3. Calculation of Results

For a given gas specimen, the *ratio* of the electrical current signals from the $^{13}CO_2^+$ and $^{12}CO_2^+$ ions is compared to that obtained when a reference CO_2 sample of known isotopic abundance is introduced into the GIRMS system under identical conditions. The result of this differential measurement is expressed as the "delta per mil" difference between the ($^{13}CO_2/^{12}CO_2$) ratio of the sample (R_B) and the reference (R_S):

$$\delta\,^{13}C = \frac{R_B - R_S}{R_S} * 1000, ‰$$

The symbol for the "delta per mil" unit is ‰.

E. Intended Use

The ABCA is a continuous flow Gas Isotope Ratio Mass Spectrometer (GIRMS) System intended for use in the measurement of stable isotopes of carbon, nitrogen, and oxygen in gas samples. For this purpose, the system is comprised of a gas sampling module, a gas purification module, and an isotope ratio mass spectrometer which are synchronously coupled by means of an external personal computer which also collects and archives data.

F. Summary of Modifications to the Predicate Device

Hardware Modifications

a) The gas purification (gas chromatograph) module, gas sampling module and the sample injector are housed in a single cabinet to reduce counter space requirements.

b) A redesigned gas sampling module allows sampling an aliquot of gas samples instead of using the entire sample. This permits re-sampling if necessary.

c) A re-sized gas chromatographic column and reduced helium carrier gas flow allow smaller samples and improved chromatographic resolution.

d) An option for *direct reference gas injection* from a reference gas cylinder eliminates the need to occupy patient sample or QC tube positions in the autosampler with reference gas tubes.

Software Modifications

a) The Microsoft Visual Basic compiler was upgraded from VB 3.0 to VB 5.0. Software was revised to compile under VB 5.0.

b) New program code was introduced for mass spectrometer operation and control of the new gas sampler.

c) Addition of a macro language enables automation of routine operations, provides easier code maintenance and facilitates research applications.

d) A modified graphical user interface facilitates data entry and data storage.

G. Substantial Equivalence

The modified ABCA GIRMS System has the following similarities to the ABCA-NT System which previously received 510(k) clearance:

1. Has the same intended use
2. Uses the same fundamental scientific technology
3. Incorporates the same basic Europa GIRMS design
4. Calibrates using the same principle
5. Calculates final results identically
6. Has substantially equivalent technical specifications

In summary, the ABCA Gas Isotope Ratio Mass Spectrometer described in this submission is substantially equivalent to the predicate device.

H. Analytical Performance Data

1. Using calculations recommended in NCCLS EP9-A, the mean systematic difference between the predicate device and the modified device at 2.4 Delta Over Baseline (DOB) on 102 breath samples from the ^{13}C-urea breath test was determined to be 0.06 DOB.

2. Using calculations recommended in NCCLS EP5-A, within-run precision at a level of -22‰ was determined to be 0.056‰ based on triplicate analyses of stable gas samples in each of 10 daily sample runs. The claimed imprecision at this level is 0.1‰.

3. The ABCA test system response function was determined to be linear throughout the range -22‰ to 232‰.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 13 1999

PDZ Europa Limited
c/o Dr. Robert F. Martin
MarChem Associates, Inc.
325 College Road
Concord, Massachusetts 01742

Re: K992163
Trade Name: ABCA-NT Gas Isotope Ratio Mass Spectrometer System
Regulatory Class: I reserved
Product Code: DOP
Dated: June 24, 1999
Received: June 25, 1999

Dear Mr. Workman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we 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). 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 (Premarket Approval), 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Under the Clinical Laboratory Improvement Amendments of 1988 (CLIA-88), this device may require a CLIA complexity categorization. To determine if it does, you should contact the Centers for Disease Control and Prevention (CDC) at (770) 488-7655.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Steven Gutman

Steven I. Gutman, M.D, M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 1

Indications for Use Statement

Device Name:

ABCA Gas Isotope Ratio Mass Spectrometer System

Indications for Use:

The ABCA is a continuous flow Gas Isotope Ratio Mass Spectrometer (GIRMS) System intended for use in the measurement of stable isotopes of carbon, nitrogen, and oxygen in gas samples. For this purpose, the system is comprised of a gas sampling module, a gas purification module, and an isotope ratio mass spectrometer which are synchronously coupled by means of an external personal computer which also collects and archives data.

Prescription Use: No

Ken Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992163