510(k) Summary

The ABCA-NT Gas Isotope Ratio Mass Spectrometer

K974322

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

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DEC 16 1997

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This 510(k) was prepared November 14, 1997

B. Device Name and Classification

Trade Name of the Device
ABCA-NT Gas Isotope Ratio Mass Spectrometer System

Common Name of the Device
Gas Isotope Ratio Mass Spectrometer System

Classification

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

C. The Predicate Device

The predicate device is the Consolidated Nier Model 21-201 Isotope Ratio Mass Spectrometer (IRMS) manufactured by Consolidated Electrodynamics Corporation, Inc., (CEC) of Pasadena, California. The instrument is a preamendment device in that it was legally marketed in the United States by CEC before May 28, 1976.

D. Description of the Device

The ABCA-NT 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-NT System includes, as physically separate modules:

- The Europa 20-20 continuous flow IRMS
- The Europa ABCA-G gas purification module (Gas Chromatograph)
- A Gilson (or equivalent) 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 Europa Scientific ABCA-NT System. During operation, the sampler moves over each tube in turn and injects a 'double needle' probe consisting of two concentric cylinders. Purified helium carrier gas blows out of a hole in the tip of the inner cylinder of the probe and flushes all of the sample gas from the sample tube through an aperture in the side of the outer cylinder of the probe to the gas purification module. Prior to injection, the probe is purged with helium to rid it of any air. This is especially important if nitrogen is to be analyzed or with very low levels of carbon dioxide.

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 (which is frequently the case), 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. For nitrogen analysis, no such 'dumping' to waste is necessary and all column effluent is allowed to pass into the IRMS.

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*

Calibration of the system is achieved by placing sample tubes containing reference gas of known isotopic composition (from NIST, for example) at the beginning and at the end of a sample run. Reference gas tubes may also be interspersed at different intermediate positions throughout a run when there is a large number of samples. This procedure also monitors any instrumental drift and corrects for it at the end of the run.

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-NT 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. Comparison of Technological Characteristics

1. *Technological Similarities of the ABCA-NT and Predicate Device*

a) The principles of operation and basic design of the two systems are equivalent.
b) Calibrations of the two systems are based on the same principles.
c) Calculations of results are identical.
d) The Craig correction for the 45 amu current is based on the same experimental and theoretical principles.
e) The technical specifications of the systems are essentially equivalent.

2. *Technological Differences Between the ABCA-NT and the Predicate Device*

a) Continuous Flow vs. Dual Inlet

The methods of introducing sample and reference gases are different for the two systems. The Europa ABCA-NT is a continuous flow system in which the gas

component for analysis, e.g., CO_2 , separated from other gas components by molecular sieve gas chromatography, is automatically and continuously presented to the IRMS module for consecutive samples and references. Only the purified gas component and helium carrier gas enter the IRMS source for ionization. Helium gas is ionized but because of the low helium mass to charge ratio, the helium ion beam causes no interference in the measurement of the CO_2 molecular ion beams at the Faraday cup collectors.

The predicate device is a dual-inlet system in which purified sample gas and reference gas are alternately introduced into the IRMS source chamber for ionization, acceleration, separation and detection.

Since the helium ion beam causes no interference in measurement of the desired isotope ratios, no systematic bias between systems is introduced due to the different modes of sample introduction.

b) Triple-collector vs. dual-collector detection systems

The Europa System uses three Faraday cup collectors while the Consolidated system uses two collectors. In the case of CO_2 studies for example, the 44 and 45 amu collectors serve the same function in both systems. The third collector in the Europa System, at 46 amu, is used to make the Craig correction to the 45 amu current. The same compensation is made in the predicate device, but not automatically. In the Consolidated unit, a separate step is required to focus and measure the 46 amu beam current on a collector previously used for another beam.

Thus, the same interference corrections are applied, but the Europa ABCA-NT System is faster and more convenient.

G. Conclusion

The ABCA-NT is Substantially Equivalent to the cited Predicate Device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 16 1997

Robert F. Martin, Ph.D.
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C/O Marchem Associates, Inc.
325 College Road
Concord, Massachusetts 01742

Re: K974322
ABCA-NT Gas Isotope Ratio Mass Spectrometer System
Regulatory Class: I
Product Code: DOP
Dated: November 14, 1997
Received: November 17, 1997

Dear Dr. Martin:

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 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/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

VIII. Indications for Use Statement

Device Name:

ABCA-NT Gas Isotope Ratio Mass Spectrometer System

Indications for Use:

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Prescription Use: No

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K074322