OSBORN GROUP, INC.
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APR 14 2000

K993787

510(k) SUMMARY

Osborn Group, Inc.

Appraise-Cardio Sample Collection Kit

November 8, 1998

Submitter Information:

Osborn Group, Inc.
19401 West 117th Street
Olathe, Kansas 66062

Submitter's Name: Gilbert P. Bourk III
Phone: (913) 390-7146

Device Name:

Proprietary Name: Osborn Group Appraise-Cardio Sample Collection Kit

Common Name: Blood Sample Collection Kit

Classification Name: Cholesterol (total) test system
Triglyceride test system
Lipoprotein test system

Predicate Device Equivalence:

Substantial equivalence is claimed to the Diabetes Technologies, Inc. Accu-Base Hemoglobin A1c Sample Collection Kit, cleared for commercial distribution per K983172.

Device Description:

The Appraise-Cardio Sample Collection Kit is a Sample Collection Kit which is sent to the patient's home after the kit has been ordered by the patient's physician. The kit consists of the following:

- A Sample Collection Tube.
- A Sample Collection Capillary Tube.
- A Sample Tube Holder Box.
- A Patient Identification Card which contains the patient's name, address, Social Security Number, information, the physician's name and phone number and a bar code number that is peeled off and affixed to the Sample Collection Tube after the sample has been taken.
- A pamphlet containing detailed information about the lipid program and instructions on how to obtain a blood sample and mail it to a laboratory.

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- A plastic zip lock bag marked "Specimen Collection Envelope" into which the Sample Collection Tube is placed.
- An absorbent pad that is contained in the Specimen Collection Envelope.
- A plastic zip lock bag marked "Waste".
- A self-adhesive envelope in which the specimen envelope is inserted and then mailed to the preprinted address on the envelope.
- A sterile lancet
- An alcohol swab
- A sterile gauze pad
- A sterile adhesive bandage
- The mailing envelope which is used to mail the above items to the patient.

The Sample Collection Tube, Sample Collection Capillary Tube, lancet, alcohol swab, gauze pad and adhesive bandage are all legally marketed, commercially available items.

After receiving the Appraise-Cardio Sample Collection Kit in the mail, the patient then collects a blood sample, using a lancet supplied in the kit or purchased separately by the patient. The blood sample is placed in the Sample Collection Tube as described in the instructions. The bar code sticker from the Patient Identification Card is then affixed to the Sample Collection Tube which is then placed in the Specimen Collection Envelope. The Patient Information Card and Specimen Collection Envelope are then placed in the mailing envelope. The mailing envelope is then sealed and sent to a laboratory for processing. When the blood sample is received by the laboratory the patient's total cholesterol, triglycerides and HDL values are measured using existing reagent kits.

Intended Use:

The Appraise-Cardio Sample Collection Kit is a prescription device indicated for use for obtaining a blood specimen which can be collected at the patient's home or at a physician's office in a sample collection tube and delivered to the laboratory by mail. This specimen is then used to determine the patient's total cholesterol, triglycerides, HDL and LDL values. The results are then mailed to the patient's physician for evaluation.

Comparison of Technological Characteristics:

Essentially, the two devices use the same basic technology, i.e., collecting a whole blood sample and analyzing it using an existing assay methodology. However, the blood parameters being measured are different for the two devices and thus the assay methodologies are different.

Summary of Device Testing:

To obtain assurance that the whole blood samples would still provide an accurate assessment of the patients' total cholesterol, triglycerides, HDL and LDL even after undergoing the extreme temperatures and humidity conditions that can be experienced by any object sent by U.S. Mail, the Appraise-Cardio Sample Collection Kit was subjected to environmental testing. The results were within acceptable limits.

Conclusions:

Based on the above, we concluded that the Appraise-Cardio Sample Collection Kit is substantially equivalent to a legally marketed predicate device and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 14 2000

Mr. Gilbert P. Bourk III
Vice President and General Counsel
Osborn Group, Inc.
14901 West 117th Street
Olathe, Kansas 66062

Re: K993787
Trade Name: Appraise-Cardio Sample Collection Kit
Regulatory Class: II
Product Code: JKA
Dated: March 10, 2000
Received: March 13, 2000

Dear Mr. Bourk:

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.

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" (21CFR 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 I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K993787

Device Name:

Appraise-Cardio Sample Collection Kit

Indications for Use:

The Appraise-Cardio sample collection kit is a prescription device indicated for use for obtaining a blood specimen which can be collected at the patient's home or at a physician's office in a sample collection tube and delivered to the laboratory by mail. This specimen is then used to determine the patient's total cholesterol, triglycerides, HDL and LDL values. The results are then mailed to the patient's physician for evaluation.

Dean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K993787

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR **Over-The-Counter Use**___
(Per 21 CFR 801.109)

(Optional Format 1-2-96)