K990899

DEC 21 1999

OSBORN GROUP, INC.
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510(k) SUMMARY

Osborn Group, Inc.

HemoChek-A1c Sample Collection Kit

March 17, 1999

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:

HemoChek-A1c Sample Collection Kit

Common Name: Hemoglobin A1c blood sample collection kit

Classification Name: Glycosylated Hemoglobin Assay

Predicate Device Equivalence:

Substantial equivalence is claimed to the EZCHEK™/HbA1c Sample Collection Kit, and to the HemoChek Sample Collection Kit, cleared for commercial distribution per K971919 and K984529, respectively.

Device Description:

The HemoChek-A1c Sample Collection Kit is a kit which is purchased by a patient a pharmacy or other retail store. The kit consists of the following:

- A Sample Card containing the proprietary filter paper that the blood sample is placed on and a place for the patient to print his/her name, address, social security number and the date the sample was collected
- A pamphlet containing detailed instructions about how to obtain a blood sample and mail it to Osborn Group, Inc.
- A specimen envelope with the words "After blood has dried, insert completed HemoChek test in this envelope. Seal flap and place in envelope" printed on it
- A self-adhesive envelope in which the card is inserted and then mailed to Osborn Group, Inc.

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- A sterile lancet
- An alcohol swab
- A gauze pad
- An adhesive bandage
- An outer package containing all of the items listed above

After purchasing the HemoChek-A1c Sample Collection Kit, the patient then prints the required information on the Sample Card and collects a blood sample, using a lancet (either the one provided in the kit, one provided by the patient's physician or one supplied by the patient). The blood sample is placed on both circles on the right hand side of the Sample Card, as described in the instructions. The Sample Card is then placed in the specimen envelope which in turn is placed in the mailing envelope provided in the kit and mailed to Osborn Group, Inc. When the blood sample is received by Osborn Group, Inc., the patient's HbA1c level is measured using existing assay methods. The results are then mailed to the patient.

Intended Use:

The HemoChek-A1c Sample Collection Kit is indicated for over-the-counter sale for use in the measurement of HbA1c on blood specimens which can be collected at the patient's home or at a physician's office on filter paper and delivered to the laboratory by mail. The HbA1c test is used in the assessment of the average blood glucose over a 10-12 week period. The results are to be evaluated by the patient and their physician. The product is not indicated for the diagnosis of diabetes mellitus.

Comparison of Technological Characteristics:

Essentially, the devices use the same basic technology, i.e., collecting a blood sample and analyzing it using an existing assay methodology. However, the physical size of the device is different thaan the EZCHEK predicate device. Also, the existing assay methodologies used are different for the device and the EZCHEK predicate device, but are the same as for the HemoChek predicate device.

Summary of Performance Testing:

Information contained in this submission demonstrates that the HemoChek-A1c performs in the same manner as the HemoChek predicate device.

Conclusions:

Based on the above, we concluded that the HemoChek-A1c Sample Collection Kit is substantially equivalent to legally marketed predicate devices and is safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

DEC 21 1999

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

Re: K990899
Trade Name: HemoChek-A1c™ Sample Collection Kit
Regulatory Class: II
Product Code: LCP
Dated: October 29, 1999
Received: November 1, 1999

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.

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

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Peter E. Maheux

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K990899

over the counter ✓

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