JAN 28 1999

K984529

OSBORN LABORATORIES
A ChoicePoint™ Company

510(k) SUMMARY

Osborn Laboratories

HemoChek Sample Collection Kit

December 18, 1998

Submitter Information:

Osborn Laboratories
19401 West 117th Street
Olathe, Kansas 66062

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

Device Name:

Osborn Laboratories HemoChek 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, cleared for commercial distribution per K971919.

Device Description:

The HemoChek Sample Collection Kit is a kit which is sent to the patient's home after the patient has been enrolled in the HemoChek program by the patient's physician. The kit consists of the following:

- A Sample Card containing the proprietary filter paper that the blood sample is deposited on, the patient's name and address, instructions on how to obtain the sample and send it to Osborn Laboratories and a place to make changes to any of the patient's information.
- A pamphlet containing a description of the HemoChek program and detailed instructions about how to obtain a blood sample and mail it to Osborn Laboratories.
- A self-adhesive envelope in which the card is inserted and then mailed to the preprinted address on the envelope.
- The mailing envelope which is used to mail the above three items to the patient.

After receiving the HemoChek Sample Collection Kit in the mail from Osborn Laboratories, the patient then collects a blood sample, using a lancet. The blood sample is placed on all three circles on the right hand side of the sample collection card, as described in the instructions. Then the card is placed in the mailing envelope provided in the kit and mailed to Osborn Laboratories. When the blood sample is received by Osborn Laboratories the patient's HbA1c level is measured using existing assay methods.

Intended Use:

The HemoChek Sample Collection Kit is indicated 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 a filter paper and delivered to the laboratory by mail. The results are to be evaluated by the patient's physician. The product is not indicated for the diagnosis of diabetes mellitus.

Comparison of Technological Characteristics:

Essentially, the two 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 two devices is different. Also, the existing assay methodologies used are different for the two devices.

Summary of Performance Testing:

To validate the accuracy and repeatability of the results obtained using the HemoChek Sample Cards, whole blood specimens were selected to obtain a range of HbA1c levels. Samples of whole blood from each specimen were analyzed using an existing assay method. Next, additional samples were obtained from each specimen using HemoChek Sample Cards and analyzed using the same assay method.

To further validate the HemoChek Sample Cards, blood specimens were taken at a local hospital from a number of persons with high levels of HgA1c. For each specimen, a sample of whole blood and a sample collected using a HemoChek Sample Card were analyzed using the same methodology used in the initial validation discussed in the previous paragraph. The variation between the whole blood value and the value obtained using a HemoChek Sample Card was within acceptable accuracy limits.

To obtain assurance that the blood samples would still provide an accurate assessment of the patients' hemoglobin A1c levels even after undergoing the extreme temperatures and humidity conditions that can be experienced by any object sent by U.S. Mail, the HemoChek Sample Collection Kit was subjected to environmental testing. The test results were considered to be within acceptable accuracy limits.

To obtain patient comments about the HemoChek Sample Collection Kit, Osborn Laboratories conducted a survey. Overall, the users were very pleased with the product.

Conclusions:

Based on the above, we concluded that the HemoChek 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
2098 Gaither Road
Rockville MD 20850

JAN 28 1999

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

Re: K984529
Trade Name: Osborn Laboratories HemoChek Sample Collection Kit
Regulatory Class: II
Product Code: LCP
Dated: December 18, 1998
Received: December 21, 1998

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

510(k) Number (if known): K984529

Device Name:

HemoChek Sample Collection Kit

Indications for Use:

The HemoChek Sample Collection Kit is indicated 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 a filter paper and delivered to the laboratory by mail. The HbA1c test is used in the assessment of the average blood glucose over an 8-12 week period. The results are to be evaluated by the patient's physician. The product is not indicted for the diagnosis of diabetes mellitus.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K984529

(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)

Home Use by Prescription

(Optional Format 1-2-96)