K050328

MAR 29 2005

510K Summary of Safety and Effectiveness of Pregnancy-Skreen™ hCG Liquid Control Urine – Positive and Negative

Submitter
Biochemical Diagnostics, Inc.
180 Heartland blvd
Edgewood, NY 11717

Telephone: 631-595-9200
Fax: 631-595-9204

Contact Person
Allen Panetz
President
Telephone: 631-595-9200
E-mail: allen@biochemicaldiagnostics.com

Date of Summary Preparation
January 27, 2005
Revision –March 17, 2005

Device Identification
Product Trade Name: Pregnancy-Skreen™
Common Name: hCG Liquid Control Urine – Negative
hCG Liquid Control Urine – Positive
Classification: Class I
Product Code: JJX Single
Regulation Code: 21 CFR 862.1660

Description of device
These products are manufactured in a liquid matrix solution prepared with negative human urine, chemicals, and preservatives. The matrix is not known to interfere with any immunoassay procedures including those used in handheld devices. The positive control is spiked in a target range of 200-400 mIU of Human Chorionic Gonadotropin per mL of urine.

Intended Use
The Pregnancy-Skreen™ controls are intended to validate the performance of qualitative hCG urine procedures and immunochromatographic devices.

Devices to which Substantial equivalence is claimed

We conducted a comparison study of the performance of Biochemical Diagnostics' Pregnancy-Skreen™ positive and negative controls with the Biorad Liquichek (k965171, k031231) and qUAntity urine controls. (k042446). The Biorad products are multi-constituent whereas Biochemical Diagnostics' control is a single constituent product designed to monitor the qualitative performance of urinalysis test procedures screening for elevated levels of hCG as an early indicator of pregnancy. The above-mentioned controls were tested on three Human Chorionic Gonadotropin (hCG) test devices. Included were the Unotech Accutest (k971886), the Quidel Card QS (k972748), and the Quidel Quickvue (k020799). Device LOD's ranged from 20-25 mIU/mL.

Acceptance Criteria

The negative and positive Pregnancy-Skreen™ controls were tested from date of manufacture to date of expiration on several devices listed above. They were run side by side with the Biorad Liquichek and qUAntity urine controls that contained hCG as one of the multiple constituents. All controls performed as expected with positive controls reading positive and negative controls reading negative.

New lots of material are run against released lots as well as against other existing controls in the market. Aliquots of the master batch are taken and stored at room temperature (18-25° C) and refrigerated at 2-8° C. testing is performed on day one and day 31. Room temperature testing serves as an accelerated test for stability of the new batch and enables QC/QA to check for cloudiness that would occur if the batch is contaminated or not properly preserved. Upon acceptance of the master batch the control is dispensed into vials, sampled according to GMP at the beginning, middle and end of run and tested on hand held devices as previously described. Key customers are periodically surveyed regarding performance of this product.

Note:

We have been forced to discontinue the quantitative testing of hCG because, to the best of our knowledge, it is no longer available from commercial reference laboratories. All quantitative testing is currently done on serum. Urine testing is limited to hand held devices. We feel confident that, considering the screening nature of the pregnancy testing and the wide range of results that constitute a positive result, combined with our testing history and acceptance criteria, we are able to produce a product that is well suited to this market without quantitative confirmation.

Stability

The urine matrix used in Pregnancy-Skreen™ (see description of device) has been used for over eleven years in our Detectabuse™ Liquid Control Urines (k925586). During this period it has proven to impart long-term stability (greater than three years) to all drugs added as well as to naturally occurring compounds. In order to validate the stability of hCG in this matrix, stability testing was performed over a two year period with a single lot # of each Pregnancy-Skreen™ control. Several other lots of this product were produced and tested from time to time during this period with identical qualitative results (positive or negative) as the long-term test lot. Aliquots of the long term lot of Pregnancy-Skreen™ controls were stored refrigerated at 2-8° C and at room temperature (18-25° C) and tested as shown in the accompanying chart. **All supporting data is on file at Biochemical Diagnostics, Inc.**

Unopened Shelf Life – Unopened controls, packaged in 5 mL bottles and sampled bi-weekly, were stable for at least 31 days (limit of study) when stored at room temperature (18-25° C) and for two years when stored refrigerated at 2-8° C.

Opened bottle stability – Opened controls were stable for at least 31 days when stored at room temperature (18-25° C) or refrigerated at 2-8° C (study limited to 31 days). Negatives remained negative and positives remained qualitatively positive. Opened controls packaged in 100 mL bottles and sampled by pouring instead of pipetting were stable for two years when stored at 2-8° C.

Preservatives

Pregnancy-Skreen™ controls (positive and negative) contain Sodium Azide in a concentration of less than 0.1%, which is below the level required for preparation of MSDS and listing on the bottle or packaging label.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

MAR 29 2005

Mr. Allen Panetz
President
Biochemical Diagnostics, Inc.
180 Heartland Blvd.
Brentwood, NY 11717

Re: k050328
Trade/Device Name: Pregnancy-Skreen ™
Regulation Number: 21 CFR 862.1660
Regulation Name: Quality control material (assayed and unassayed)
Regulatory Class: Class I
Product Code: JJX
Dated: February 8, 2005
Received: February 9, 2005

Dear Mr. Panetz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 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 information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (240)276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address
http://www.fda.gov/cdrh/industry/support/index.html

Sincerely yours,

Jean M. Cooper MS, DVM

Jean M. Cooper, MS, D.V.M.
Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K050328

Device Name: Pregnancy-Skreen™
Indications for:

The Biochemical Diagnostics, Inc., Pregnancy-Skreen™ urine controls are intended to validate the performance of qualitative hCG methods. They should be treated as any "unknown" specimen while following the specific protocol of the assay being used. This product is intended to be used by health care professionals as an integral part of good laboratory practices.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 791 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson

Division Sign-Off

Office of In Vitro Diagnostic
Device Evaluation and Safety

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