510 (K) SUMMARY

Date of Summary: October 7, 1999

Product Name:

One-Step Double-Chek™ Pregnancy Test

Sponsor:

Bio-Medical Products Corp.
10 Halstead Road
Mendham, NJ 07945

Correspondent:

MDC Associates
Fran White
Regulatory Consultant
15 Oak Street
Beverly Farms, MA 01915

Substantially Equivalent Devices:

Product: Abbott TestPack Plus
Manufactured by: Abbott Diagnostics

PRODUCT DESCRIPTION:

The One-Step Double-Chek™ Pregnancy Test is to be used for detecting human Chorionic Gonadotropin (hCG) in urine and serum. The presence of hCG usually appears about the seventh day after fertilization. The One-Step Double-Chek™ Pregnancy Test will detect hCG in urine and serum at a concentration level of 25 mIU/ml. The One-Step Double-Chek™ Pregnancy Test will be sold for professional use only.

INTENDED USE:

The One-Step Double-Chek™ Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine and serum, for the early detection of pregnancy. For Laboratory Professional Use Only.

SUMMARY OF TECHNOLOGY:

The One-Step Double-Chek™ Pregnancy Test employs a unique combination of monoclonal-dye conjugate and polyclonal-solid phase antibodies to selectively identify human Chorionic Gonadotropin (hCG) in urine and serum. As the urine or serum sample flows through the absorbent portion of the device, the antibody-dye conjugate binds to the hCG forming an antibody-antigen complex. This complex binds to the anti-hCG antibody in the positive reaction zone and produces a pink-rose color band if hCG concentration is equal to or greater than 25 mIU/ml. In the absence of hCG, there is no line in the reaction zone. Unbound conjugate binds to the reagents in the control zone, producing a pink-rose color band, demonstrating that the reagents are functioning correctly.

PERFORMANCE DATA:

A clinical trial was done to compare the performance of the One-Step Double-Chek™ Pregnancy Test. These data clearly demonstrates the performance of the One-Step Double-Chek ™ Pregnancy Test by Bio-Medical is substantially equivalent to the Abbott TestPack Plus ™.

Sensitivity =	100%
Specificity =	100%
Agreement =	100%

STATEMENT OF SAFETY AND EFFICACY:

The One-Step Double-Chek™ Pregnancy Test when compared with another commonly used pregnancy test (Abbott TestPack Plus) demonstrated 100% performance.

All pregnancy results were confirmed by physical examination and/or ultrasound.

These data clearly demonstrate the safety and efficacy of the One-Step Double-Chek Pregnancy Test and further confirm that the accuracy, sensitivity and specificity of this product when compared to a substantially equivalent device currently being sold for professional use. A trained Laboratory Technician performed testing in a CLIA registered laboratory.

Bio-Medical Products Corporation confirms that any/all data provided in this submission may be released upon request.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

NOV 18 1999

Biomedical Products Corporation
c/o Ms. Fran White
MDC Associates
15 Oak Street
Beverly Farms, Massachusetts 01915

Re: K992915
Trade Name: One-Step Double-Chek™ Pregnancy Test
Regulatory Class: II
Product Code: JHI
Dated: October 7, 1999
Received: October 21, 1999

Dear Ms. White:

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) K992915
Device Name: One-Step Double-Chek™ Pregnancy Test

Indication for Use:

The One-Step Double-Chek™ Pregnancy Test is a test for the qualitative determination of human chorionic gonadotropin (hCG) in urine and serum, for the early detection of pregnancy. For Laboratory Professional Use Only.

Jean Cooper
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K992915

(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)**