K971921

JUN 24 1997

MONOBIND, INC.

May. 21, 97

510(k) Summary

Dear Sir:

Monobind Inc., registration number 2020726, plans to introduce into commercial distribution an enzymeimmunoassay (IEMA) kit for the determination of prolactin (PRL) in human serum.

The proprietary name is Prolactin (PRL) ELISA and the usual name is PRL IEMA. This device classification name is - prolactin test system - product code CFT (per 21 CRF section 862.1625).

This device is substantially equivalent to the Ciba Corning ACS 180 chemiluminescence (ICMA) test, which predicates the new device.

The contact individual for this submission is Dr. Frederick R. Jerome.

The Monobind ELISA method is based on two-site immunoassay (sandwich) technology utilizing the streptavidin-biotin reaction to effect separation. Upon mixing monoclonal biotinylated anti-PRL antibody, the enzyme-labeled anti-PRL antibody and a serum containing the native antigen (PRL), reaction results between the native antigen (PRL) and the antibodies, without competition or steric hindrance, to form a soluble sandwich complex. Simultaneously, the complex is deposited to the well through the high affinity reaction of streptavidin and biotinylated antibody. After incubation is complete, decantation or aspiration separates the bound fraction. The enzyme activity on the well is directly proportional to the native antigen (PRL) concentration. By utilizing several different serum references of known antigen values, a dose response curve can be generated from which the antigen concentration of an unknown can be ascertained.

The intended use of the device: The quantitative determination of prolactin (PRL) concentration in human serum by a microplate enzymeimmunoassay.

The technological characteristics of the new device compared to the predicate device are very similar. This includes the use of two-site immunoassay (sandwich) technology using monoclonal and polyclonal antibodies, and human serum prepared calibrators (standardized against the same international reference material). The main difference resides in the use of an enzyme tracer compared to chemiluminescence as well as magnetic particles versus streptavidin coated polystyrene wells.

Substantial equivalency was based on clinical comparison (linear regression), using 86 specimens from normal (including pregnancy) and disease states' populations. The mean values for reference method (ICMA) and this method (microplate IEMA) are 17.3 ng/ml and 19.0 ng/ml respectively. The equation to a straight line [y= 1.01 (x) +1.63] and correlation coefficient (0.973) indicates good method agreement.

In addition recovery data demonstrated an average recovery of 102.7% when exogenous added prolactin was introduced into human serum specimens. Similarly, linearity studies showed an average 96.7% when specimens were diluted and compared to the dose response curve.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUN 2 4 1997

Dr. Frederick R. Jerome
Monobind, Inc.
729 West 16th Street
Costa Mesa, California 92627

Re: K971921
Prolactin (PRL) Hormone Microplate ELISA
Regulatory Class: I
Product Code: CFT
Dated: May 22, 1997
Received: May 23, 1997

Dear Dr. Jerome:

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 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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/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

Indications for Use Statement

510(k) Number (if known): K971921

Device Name: Prolactin (Prl) Hormone ELISA

The Quantitative Determination of Prolactin Hormone Concentration in Human Serum by a Microplate Immunoenzymometric assay. Measurements obtained by this device are used in the diagnosis and treatment of disorders of the anterior pituitary gland or the hypothalamus portion of the brain.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K971921

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Folmat 1-2-96)