K973720

SEP - 2 1997

MONOBIND, INC.
Jul. 11, 97

510(k) Summary

Dear Sir:

Monobind Inc., registration number 2020726, plans to introduce into commercial distribution an enzymeimmunoassay (ELISA) kit for the determination of follicle-stimulating hormone (FSH) in human serum and plasma.

The proprietary name is Follicle-stimulating hormone (FSH) ELISA and the usual name is FSH ELISA. This device classification name is - follicle-stimulating hormone test system - product code CGJ (per 21 CRF section 862.1300).

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-FSH antibody, the enzyme-labeled anti-FSH antibody and a serum containing the native antigen (FSH), reaction results between the native antigen (FSH) 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 (FSH) 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 follicle-stimulating hormone (FSH) concentration in human serum and plasma by a microplate enzymeimmunoassay. Measurements of FSH are used in the diagnosis of pituitary gland and gonadotropin disorders.

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 128 specimens from low to elevated populations. The values ranged from 0.1 – 133 mIU/ml.The mean values for reference method (ICMA) and this method (microplate ELISA) are 21.0 mIU/ml and 18.0 mIU/ml respectively. The equation to a straight-line [y= 0.93 (x) - 1.5] and correlation coefficient (0.994) indicates good method agreement.

In addition recovery data demonstrated an average recovery of 99.9% when exogenous added follicle-stimulating hormone was introduced into human serum specimens. Similarly, linearity studies showed an average 93.8% when specimens were diluted and compared to the dose response curve.

729 West 16th Street , Costa Mesa , CA (USA) 92627 Phone: (714) 642-4830 FAX: (714) 650-8459

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP - 2 1997

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

Re: K972720
Follicle Stimulating Hormone (FSH) ELISA
Regulatory Class: I
Product Code: CGJ
Dated: July 14, 1997
Received: July 21, 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 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/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): _____

Device Name: Follicle Stimulating Hormone (FSH) Microplate EIA

The quantitative determination of follicle stimulating hormone (FSH) concentration in human serum and plasma by a microplate enzymeimmunoassay.Measurements of follicle-stimulating hormone are used in the diagnosis of pituitary gland and gonadotropin disorders.

(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 K972720

Prescription Use ✓ OR Over-The-Counter Use _____

(Per 21 CFR 801.109)

(Optional Folmat 1-2-96)