K 031870

BECKMAN COULTER

510(k) Summary

JUL 1 5 2003

1.0 Submitted By:

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Beckman Coulter, Inc.
200 S. Kraemer Blvd. W-104
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2.0 Date Submitted

June 16, 2003

3.0 Device Name(s):

3.1 Proprietary Names

SYNCHRON® Systems Valproic Acid Reagent

3.2 Classification Names

Neuroleptic drugs radioreceptor assay test system (21 CFR § 862.3645)

4.0 Legally Marketed Device

The SYNCHRON Systems Valproic Acid (VPA) Reagent claims substantial equivalence to the Beckman Coulter SYNCHRON Systems VPA Reagent currently in commercial distribution, FDA 510(k) Number K961256.

5.0 Device Description

The SYNCHRON Systems VPA Reagent is designed for optimal performance on the SYNCHRON CX (CX4/4CE/4Δ/4PRO, CX5/5CE/5Δ/5PRO, CX7/7RTS/7Δ/7PRO, CX9ALX/9PRO) and SYNCHRON LX (LX20/PRO/LXi) Systems. The reagent kit contains two 100-test cartridges, and is packaged separately from the associated calibrators.

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6.0 Intended Use

Valproic Acid (VPA) Reagent, in conjunction with the SYNCHRON® Systems Drug Calibrator 1 set, is intended for the quantitative determination of valproic acid concentration in human serum or plasma on SYNCHRON Systems.

7.0 Comparison to the Predicate (Description of the Modification to the Legally Marketed Device)

The modification to the SYNCHRON Systems VPA assay involves a non-reactive ingredient change to the reagent formulation, optimization of the operating parameters on the LX (LX20/PRO/LXi) instrument platform, and updated performance claims (equivalency, precision) in the product inserts.

8.0 Summary of Performance Data

Performance data from validation testing supports equivalency.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JUL 15 2003

Ms. Mary Beth Tang
Staff Regulatory Affairs Specialist
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Brea, CA 92822-8000

Re: k031870
Trade/Device Name: SYNCHRON® Systems Valproic Acid Reagent
Regulation Number: 21 CFR 862.3645
Regulation Name: Neuroleptic drugs radioreceptor assay test system
Regulatory Class: Class II
Product Code: LEG
Dated: June 16, 2003
Received: June 17, 2003

Dear Ms. Tang:

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 (301) 594-3084. 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/dsma/dsmamain.html.

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): To be assigned K031870

Device Name: **SYNCHRON® Systems Valproic Acid Reagent**

Indications for Use:

Valproic Acid (VPA) Reagent, in conjunction with the SYNCHRON® Systems Drug Calibrator 1 set, is intended for the quantitative determination of valproic acid concentration in human serum or plasma on SYNCHRON Systems.

Valproic Acid is an anticonvulsant drug. It is indicated for the treatment of absence (petite mal), generalized tonic-clinic and myoclonic seizures. Valproic Acid therapy is monitored for suspected inadequate dose or toxicity.

Valproic Acid Reagent is used to measure the valproic acid concentration by a particle enhanced turbidimetric inhibition immunoassay method.

(b) Classification. Class II.

(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

Division Sign-Off

Office of In Vitro Diagnostic Device Evaluation and Safety

510(k) K031870