Wyntek diagnostics

8. 510 (k) Summary

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Submitter : Wyntek Diagnostics, Inc.
6146 Nancy Ridge Dr. Ste. 101
San Diego, CA 92121
Tel: 619-452-3198
Fax: 619-452-3258

AUG 26

Contact Person: Shu-Ching Cheng

Product Name:

Proprietary Name:	OSOM™ Mono Test
Common Name:	Mono Test
Classification Name:	System, Test, Infectious mononucleosis
Classification Number:	82KTN

Intended Use: OSOM™ Mono Test is intended for the qualitative determination of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aids in the diagnosis of infectious mononucleosis .

Description: OSOM Mono Test uses color immunochromatographic technology with bovine erythrocyte extract coated on the membrane. If the specific IM heterophile antibody is present in the sample, a visible blue test line will appear to indicate a positive result.

Substantial Equivalence:
OSOM Mono Test is substantially equivalent to Meridian's MonoSpot Latex Test and Pacific Biotech's CARDS OS Mono Test. All three tests are rapid tests for the qualitative determination of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood except that MonoSpot Test can not be used for whole blood. All three tests aid in the diagnostics of infectious mononucleosis.

Applicant Signed: S.C. Cheng Date: 6/13/97
Shu-Ching Cheng

Appendix I -Directional Inserts Used for Assay Comparisons:

- MonoSpot Latex – Meridian Diagnostics, Inc.
- CARDS OS Mono Test - Pacific Biotech, Inc., a subsidiary of Quidel Corp.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Mr. Shu-Ching Cheng
Vice President, Operations
Wyntek Diagnostics, Inc.
6146 Nancy Ridge Drive, Suite 101
San Diego, California 92121

AUG 26 1997

Re: K972231
Trade Name: OSOM™ Mono Test
Regulatory Class: II
Product Code: KTN
Dated: June 13, 1997
Received: June 16, 1997

Dear Mr. Cheng:

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 requirement, 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 at (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

2. Device Indications For Use

510 (k) Number: To-Be-Assigned

Device Name: OSOM™ Mono Test

Indication For Use:

The OSOM™ Mono Test is intended for the qualitative detection of infectious mononucleosis heterophile antibodies in serum, plasma or whole blood as an aid in the diagnosis of infectious mononucleosis.

(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 _____

Prescription Use ✓ OR Over-The-Counter Use____
(Per 21 CFR 801.109)