K973940

AUG 10 1998

510(k) Summary

Contact	Bryan Kiehl
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Date:	10 August, 1998

Device Name	ImmunoWELL VCA IgG Test
Common, usual, or classification name	Epstein-Barr Virus Viral Capsid Antigen IgG Test
Classification Number (if known)	866.3235

Identification of the legally marketed device substantial equivalence is claimed:

Epstein-Barr Viral Capsid Antigen IgG ELISA Kit, Gull Laboratories, Inc.

Description of the new device:

Microtiter ELISA kit detecting VCA IgG antibodies

Intended Use of New Device:

ImmunoWELL VCA IgG Test is for the qualitative detection of IgG antibody to Epstein-Barr Virus viral capsid antigen (VCA) in human serum by ELISA. When the VCA IgG test is used in conjunction with other testing such as the EBV nuclear antigen (EBNA-1), VCA IgM, and EBV early antigen tests and/or heterophile tests, the results can serve as an aid in the diagnosis of infectious mononucleosis (IM).

Technological characteristics of the new device compared to the predicate device:

The new device and the predicate EIA device are essentially identical. Both use VCA antigens and measure antibodies in a microtiter assay format using ELISA technology.

Non-clinical performance data, the summary includes a brief discussion of the nonclinical tests and how their results support a determination of substantial equivalence.

The predicate device and the new device perform essentially the same when testing sera from suspected patients. The observations are:

Table 1: Gull EIA

		Alternate EIA		
		Past/Recent	Current	No Past Infection
ImmunoWELL	Past/Recent	65	8	0
	Current	0	7	0
	No Past Infection	5	1	8

Clinical performance data, the summary includes a brief discussion of clinical tests and how their results support a determination of substantial equivalence.

The device used in conjunction with other ImmunoWELL EBV assays (EBNA IgG and VCA IgM) provides clinical information that is substantially the same as serological information using the predicate device.

The summary includes the conclusions drawn from the nonclinical and clinical tests.

This assay yields results that are essentially the same the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

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Bryan L. Kiehl, Ph.D.
Vice President
GenBio
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San Diego, California 92128

Re: K973940/S2
Trade Name: ImmunoWELL® EBV VCA IgG Test
Regulatory Class: I
Product Code: LSE
Dated: May 15, 1998
Received: May 19, 1998

Dear Dr. Kiehl:

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.

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

FDA Document Number:

Indications for Use

510(k) Number (if known): K973940

Device Name: ImmunoWELL VCA IgG Test

Indications for Use: ImmunoWELL VCA IgG Test is for the qualitative detection of IgG antibody to Epstein-Barr Virus viral capsid antigen (VCA) in human serum by ELISA. When the VCA IgG test is used in conjunction with other testing such as the EBV nuclear antigen (EBNA-1), VCA IgM, and EBV early antigen tests and/or heterophile tests, the results can serve as an aid in the diagnosis of infectious mononucleosis (IM).

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Woody Dubois
(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973940

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ____

(Optional Format 1-2-96)