K971508

SEP 17 1997

510(k) SUMMARY

BioWhittaker, Inc.
8830 Biggs Ford Road
Walkersville, MD 21793
(301) 898-7025

Contact: **Leif E. Olsen**
Vice President Regulatory Affairs

Device: **RhMK II, (Expanded Primary Rhesus Monkey Kidney Cell Culture)**

Intended Use: BioWhittaker's RhMK II is intended to be used as an alternative to the use of Primary Rhesus Monkey Kidney Cell Culture. Use of these cells increases the yield possible from each kidney and reduces the number of animals required to satisfy cell requirements.

Device Function: Cultures of live cells are the most convenient host system for the cultivation of viruses. After inoculation of the culture with a clinical specimen and incubation, the culture is observed for evidence of viral replication. Infection by virus can result in the development of characteristic cytopathic effect (CPE) and / or hemadsorption, or staining with specific virus fluorescent antibody markers.

Device Performance: Infectivity comparison testing between BioWhittaker's Primary Rhesus Monkey Kidney Cell Culture (a pre-1976 device) and RhMK II, an expanded Primary Rhesus Monkey Kidney Cell Culture demonstrates similar sensitivity to the inoculated viruses polio 1, coxsackie B1, influenza A, parainfluenza 2, measles and mumps.

Conclusion: BioWhittaker's RhMK II is safe and effective, performing as well as the currently available Primary Rhesus Monkey Kidney Cell Culture for viral isolation in clinical specimens.

Preparation Date: April 22, 1997

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 17 1997

Leif E. Olsen
Vice President
Regulatory Affairs
Bio-Whittaker, Inc.
8830 Biggs Ford Road
Walkersville, Maryland 21793-0127

Re: K971508
Trade Name: RhMK II Cell Culture
Regulatory Class: I
Product Code: KIR
Dated: July 15, 1997
Received: July 16, 1997

Dear Mr. Olsen:

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.

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

510(k) Number (if known): K971508

Device Name: RHMK II Cell Culture

Indications For Use:

RHMK II is intended for use in the isolation and identification of virus in various clinical specimens from patients suspected of having a viral infection.

(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 K971508

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

(Optional Format 1-2-96)