K973204

510(k) Summary

SEP 25 1997

a.1. Diagnostic Hybrids, Inc.
1 President Street
Athens, OH 45701
(614)593-1784
FAX:(614)593-0980
Attn: J.L. Brown
Date of Preparation: June 10, 1997

a.2. Trade Name: **FreshCells™**
Classification Name: Cells, Animal and Human, Cultured.

a.3. A predicate device is that of BioWhittaker, marketed as cell cultures, Appendix II, pp. A-11 to A-13 of this 510(k) Notification.

a.4. The subject device provides HEL, HFF, LLC-MK_2, Mv1Lu, NCI H292, Vero and WI-38 cells (in addition to MRC-5, McCOY, BGMK, and CV-1, under 510(k) K936271 and A549 and HEp-2, under 510(k) K962306 which have previously been cleared for marketing under the same name, **Fresh Cells™**) as nearly confluent monolayers ready for use upon receipt after a short pre-incubation period.

a.5. Intended Use: Cell cultures to be used as hosts for the isolation and identification of specific viruses. The subject of this 510(k) Notification, the cell lines HEL, HFF, LLC-MK_2, Mv1Lu, NCI H292, Vero and WI-38 are susceptible to and can be used in the isolation and confirmation of the following viruses from clinical samples:

CELL LINE/ORIGIN	SPECIFIC VIRUSES
HEL/Human Embryonic Lung	Adenovirus, CMV, Echovirus, HSV, Poliovirus, Rhinovirus, Vesicular stomatitis (Indiana Strain) virus and VZV.
HFF/Human Foreskin Fibroblasts	Adenovirus, CMV, Echovirus, HSV, Mumps, Poliovirus, Rhinovirus, VZV.
LLC-MK_2, Original/Rhesus Monkey Kidney	Poliovirus type 1, Enterovirus, Rhinovirus, Myxovirus and Poxvirus groups.
Mv1Lu/Mink Lung	HSV, CMV.
NCI-H292/Human, Pulmonary muco-epidermoid carcinoma.	Vaccinia virus, HSV, Adenovirus, BK polyomavirus, Reoviruses, Measles virus, RSV, some strains of Influenza type A, most Enteroviruses and Rhinoviruses, Parainfluenza and Mumps.
Vero/African Green Monkey	Adenovirus, Coxsackie B, HSV, Measles, Mumps, Poliovirus type 3, Rotavirus, Rubella
WI-38/Human Lung	Adenovirus, CMV, Echovirus, HSV, Influenza, Mumps, Poliovirus, Rhinovirus, RSV, VZV.

a.6. A comparison of Technological Characteristics:

Characteristics	Predicate Device	Subject Device
Source of Cell Line.	ATCC or another approved supplier.	Same as predicate device.
Provided as nearly confluent monolayers.	Cells are provided routinely as nearly confluent monolayers.	Same as predicate device.
Intended Use.	Isolation & Confirmation of specific viruses.	Same as predicate device.

b.1. The non-clinical tests consist of those used to characterize the product such as appearance, growth characteristics, sterility, isoenzyme analysis and virus susceptibility.

b.2. Not applicable.

b.3. Not applicable.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

James L. Brown
Vice President
Product Development and
Regulatory Affairs
Diagnostic Hybrids, Inc.
One President Street
Athens, Ohio 45701

SEP 25 1997

Re: K973209
Trade Name: Fresh Cells™ Vero
Regulatory Class: I
Product Code: KIR
Dated: August 22, 1997
Received: August 27, 1997

Dear Mr. Brown:

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 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: **FreshCells™** in Multiwell Plates, Shell Vials and Tubes.

Indications for Use: **FreshCells™** are indicated for use in the isolation of various viruses and *Chlamydia* from clinical specimens. Viruses and *Chlamydia* are intracellular parasites which can be cultured or grown only in specific cellular hosts. They cause a variety of diseases in man with some virus infections being lethal, particularly if the individual is immunocompromised. With the introduction of several new and specific antiviral drugs over the last several years, the need to determine the identity of the viral agent has become even more important. Culture of viruses in specific cell lines has become the standard for the identification of these viruses.

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K973209

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)