510(K) SUPPLEMENT SUMMARY
April 1999

K991303

COMPANY NAME AND ADDRESS

Vista Medical Technologies
134 Flanders Road
Westborough, MA. 01581

CONTACT PERSON

Vicki Anastasi
Regulatory Affairs Manager
Telephone (508) 366-3668
Fax: (508) 366-1543

DEVICE TRADE NAME

Vista ORPC with Infomatix IntraOp

COMMON NAME

Stereo Viewing Monitor Display for Endoscopic Visualization

PREDICATE DEVICE

Vista Head Mounted Display System
With Infomatix Software, Version 1.0
K973436
Vista Medical Technologies, Inc.
134 Flanders Road
Westborough, MA 01581

When compared to the originally submitted device, the Vista ORPC with Infomatix IntraOp Software does not incorporate any significant change in intended use, method of operation, material or design that could effect the safety or effectiveness of the subject device.

DEVICE DESCRIPTION

The Vista ORPC System with Infomatix IntraOp software now features the capability to control the image display with auxiliary input devices such as a touchscreen, mouse/touchpad, and a remote keypad, as well as with voice control. Color, hue, contrast and brightness for the video sources are now adjusted via the auxilliary input devices. Another new feature of the device is the capability to capture intra-operative static images of what is being displayed on the HMD. The last captured image can be displayed to the HMD as a picture-in-picture for review. The captured images can also be exported to a CD data storage disk via a CD-RW device. The capture and display last capture functions can be operated via voice control or the auxilliary input devices. The export feature is controlled via mouse, or the touchscreen. The system also allows the VGA monitor to display what is being seen in the HMD or the user interface controls on the desktop.

INTENDED USE

The Vista ORPC with Infomatix IntraOp Software is designed to display video images while mounted on the users' head. These video images can be captured, redisplayed as still images, and exported to removable media. The ORPC with Infomatix IntraOp software is designed to be used as a personal replacement for surgical monitors.

PERFORMANCE DATA

The Vista Head Mounted Display System was designed and will be tested in compliance with the requirements of the following standards:

IEC 60601-1	General requirements for safety.
IEC 60601-1-1	Collateral standard: Safety requirements for medical electrical systems.
IEC 60601-1-2	Collateral standard: Electromagnetic compatibility requirements and tests.
UL2601-1	Standard for Safety, Medical Electrical Equipment, Part 1: General Requirements for Safety

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 12 1999

Ms. Vicki S. Anastasi
Regulatory Affairs Manager
Vista Medical Technologies, Inc.
134 Flanders Road
Westborough, Massachusetts 01581

Re: K991303
Trade Name: Vista ORPC with Infomatix IntraOp Software
Regulatory Class: II
Product Code: GCJ
Dated: April 15, 1999
Received: April 16, 1999

Dear Ms. Anastasi:

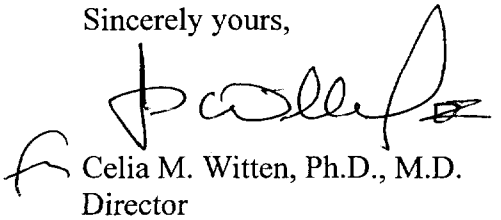
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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.

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) 594-4595. 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,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): not available K991303

Device Name: Vista ORPC with Infomatix IntraOp Software

Indications for Use:

The Vista ORPC with Infomatix IntraOp Software is designed to display video images while mounted on the users' head. These video images can be captured, redisplayed as still images, and exported to removable media. The ORPC with Infomatix IntraOp software is designed to be used as a personal replacement for surgical monitors.

(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 General Restorative Devices
510(k) Number K991303

Prescription Use X or Over-The-Counter Use ____