K981999

SEP 4 1998

Section 2

" 510(k)" Summary

Device Trade Name
Albacomp Personal Monitor

Common/Usual Name
Head Mounted Display
Virtual Display Device

Classification Name
Accessory to Endoscopes

Contact Person:
Julius L. Kluger
Albatech, Inc.
1408 S.W. 13th Court
Pompano Beach, Florida 33069
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Predicate Device:
Trade Name: MedVision Personal Monitor Models A & B
Manufacturer: AlbaComp Computers Corp.
H-8000 Szekesfehervar, Hosszuseta Ter 4 - 6
Hungary

510(k) # K961343

Summary Preparation Date: June 3, 1998

Statement of Intended Use
The Albacomp Personal Monitor is intended to display video images while mounted on the user's head.

Device Description
In endoscopic procedures the conventional video monitors are placed away from the site of the operation. As a result, the surgeon has to constantly divide his/her attention between the conventional monitor that shows the endoscopic image and the site of the operation. The remote location of the monitor and its orientation in the surgical setting have an effect on both the doctor's perception of the surgical field, and the difficulties encountered when interacting with it. Much of the difficulty encountered by a surgeon when learning the techniques of videoendoscopy, relates to the disconnection between instrument movements on the video monitor and the doctor's hand movements. With the displacement and axial rotation of the monitor, the doctor must re-learn the image to tissue relationship at each procedure, and witheach manipulation of the camera. With this decoupled image, the hand-eye coordination of the doctor suffers. For example, with a 90 degree rotation of the camera, an intended movement South to North direction, will result in a display movement in an East to West direction, presenting the doctor with a working field that is difficult to comprehend.

The Albacomp Personal Monitor projects a high resolution color video image that appears in the surgeon's line of sight in a viewing angle comparable to watching a 26" television from 2 meters (6.5 feet) away. The video image is see-around; it blocks only the area where the image appears; otherwise users are free to view the surrounding environment. The Albacomp Monitor provides an added convenience to surgeons compared to conventional monitors. The device enables the surgeon to maintain the endoscopic image in the surgeon's line of site regardless of where he/she is looking. The Albacomp Personal Monitor can receive video signals from any video source. The signals are converted in the controller unit into signals the driving electronics of LCD displays require.

The Albacomp Personal Monitor is a monoscopic binocular displays with a relatively narrow field of vision. The Albacomp Personal Monitor takes standard video signals and displays them on a small TFT-LCD display that can be connected to any standard video source. The Albacomp Personal Monitor consists of a monitor block, eyeglasses, cable and controller box. The monitor block contains the display for Albacomp Personal Monitor, a backlight and its driver for the LCD, and a system of lenses and mirrors that project the display image onto the retina of the eyes. The light beams coming from the display are reflected in two directions by dividing mirrors placed in front of the display. The monitor block has a mounting slot that fits into the vertical nose piece of the eyeglasses. The controller box contains the video input demodulator unit and the driving electronics of the LCD display. The LCD direct display control signals are sent through a flexible shielded cable to the displays.

The eyeglasses have adjustable temple pieces and each unit comes with a commercially available 9V AC-DC adaptor with low EMI.

All components and accessories of the device are marketed as non-sterile.

Device Comparison

The Albacomp Personal Monitor is substantially equivalent to the MedVision Personal monitor Models A & B, which received clearance from the FDA March 13, 1997 (K961343). The Albacomp Personal Monitor , also is substantially equivalent to the display component of Vista Medical Technologies' Head Mounted Display, which received clearance from the FDA on September 11, 1996 (K961800). The Albacomp Personal Monitor is a binocular monoscopic display with a single LCD display. The MedVision Personal Monitor Models A & B are the virtually the same, but the MedVision also has an AMEL display available. The Vista Medical Technologies' Head Mounted Display has two AMLCDs and it is a monoscopic/ stereoscopic display. The predicate device, as well as the Albacomp Personal Monitor have relatively narrow field of view and relatively higher and apparent resolution. The predicate device and the Albacomp Personal Monitor are monoscopic displays that do not need the large virtual distance, large field of view to create the stereoscopic immersion as opposed to the Vista Medical Technologies' head mounted display. The tradeoff for the large field of view is the reduction in apparent resolution.

Safety

The Albacomp Personal Monitor is designed, manufactured and tested in compliance with IEC-601-1, IEC-601-2, and IEC 10004-3.

The eyeglasses will have polycarbonate lenses to ensure high resistance to impact and scratch.

When compared to the predicate device, the Albacomp Personal Monitor does not incorporate any significant change in intended use and technological characteristics that could affect the safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 4 1998

Albatech, Inc.
c/o Sheryl S. Natelson, P.A.
4700 Sheridan Street
Building J
Hollywood, Florida 33021

Re: K981999
Trade Name: Albatech Personal Monitor
Regulatory Class: II
Product Code: GCJ
Dated: June 3, 1998
Received: June 8, 1998

Dear Ms. Natelson:

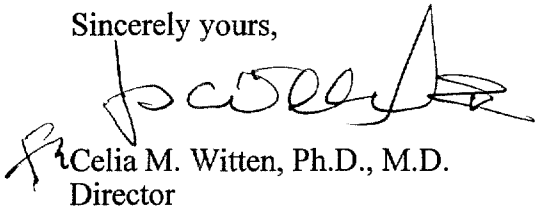
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Albatech, Inc.
1408 S.W. 13th Court
Pompano Beach, Florida 33069

April 29, 1998

Section 1

Statement of Indication for Use

The Albatech Personal Monitor is intended to display video images while mounted on the user's head.

Prescription Use X
(Per 21CFR 801.109)

or

(Division Sign-Off)
Division of General and Restorative Devices
510(K) Number

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K981797