

K961800

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**510(K) SUMMARY**  
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**COMPANY NAME AND ADDRESS**

Vista Medical Technologies  
5451 Avenida Encinas, Suite A  
Carlsbad, CA. 92008

**CONTACT PERSON**

Debbie Iampietro  
Director of Regulatory Affairs and Quality Assurance

Telephone (508) 366-8882  
Fax: (508) 366-8858

**DEVICE TRADE NAME**

Head Mounted Display

**COMMON NAME**

Stereo Viewing Monitor  
Display for Endoscopic Visualization

**PREDICATE DEVICE**

1. Device Name: 3DSCOPE™ Three Dimensional Medical Video System  
Classification: Camera, Television, Endoscopic, without audio  
Manufacturer: American Surgical Technologies  
300 Billerica Rd  
Chelmsford, MA 01824  
510(k) #: K923160
2. Device Name: Crystal Eyes View/Record and Playback Controllers with Eyewear and Emitters  
Classification: Endoscope and Accessories, Class II per 21 CFR 876.1500  
Manufacturer: Oktas  
134 Flanders Rd.  
Westborough, MA 01581  
510(k) #: K944254

## DEVICE DESCRIPTION

The Head Mounted Display (HMD) System is a binocular field display, occupying a large portion of the normal straight ahead field of view. This display is intended to be used as a component of a visualization system for use in endoscopic surgery. Traditional video-endoscopic surgery images are displayed on a TV monitor. This requires the surgeon to maintain contact with the traditional monitor and remain in position with it at all times. Having to turn away from the monitor causes the surgeon to lose sight of what is being accessed. The HMD system enables the surgeon to see the surgical site as well as the general operating field with the lateral and 45 degree look down vision, without having to look away, thus providing the means to present the endoscopic picture in a more natural and acceptable look down location with respect to the patient. This also provides a safe back up, the physician can resort to either direct visualization or utilize the back up 2D video monitor. The HMD takes a standard signal and displays it on two small electronic image display devices called liquid crystal display (LCD). It can be connected to any standard video generating equipment.

The HMD consists of an image generating array, eyepiece, and electronics. The image generating array is an active matrix liquid crystal display (LCD). These elements are mounted on a lightweight and compact headgear which fits comfortably on the user's head. The remaining electronics are housed separately in a controller station. The HMD communicates with the controller by a lightweight, durable, flexible cable. The HMD can be driven by both monocular and stereo endoscopes.

The HMD Controller will accept NTSC, PAL with CVBS, or S Video (Y,C) video input. Interfaces to external and remote data sets, power supplies and drivers for the LCD and backlight are included in the controller. A maximum of four (4) HMDs and two (2) standard video monitors can be driven simultaneously with the single controller.

## INTENDED USE

The Vista Head Mounted Display System is designed to display video images while mounted on the users head.

## DEVICE COMPARISON

The HMD system is similar to the display component of the 3DSCOPE™, Three Dimensional Medical Video System which received clearance from FDA in December 1992, (K923160). The 3DSCOPE™ Stereo Display is a high resolution, high speed, multi-synch RGB full color video display monitor. The liquid crystal screen switches its circular polarization from left to right in precise synchronization (120 Hz) with the left and right images that appear on the Stereo Display. When the left image appears on the Stereo Display, the liquid crystal shutter switches to the left polarized state.

The HMD system accepts mono or binocular input from the endoscope and passes the input to the LCD matrix. The small number of elements, compactness and low weight enable this technology to be incorporated into a head mounted display. Most endoscopes are optical and attached to the video system which can feed the video electronic imager rather than an optical image from the endoscope itself to the HMD.

Corrective eyewear may be worn with this device as the HMD provides large eye relief.