MAY 19 1999

**510(K) SUMMARY**
**February 1999**

K990635

COMPANY NAME AND ADDRESS

Vista Medical Technologies
134 Flanders Road
Westborough, MA. 01581

CONTACT PERSON

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

DEVICE TRADE NAME

Vista StereoScope System

COMMON NAME

Video Camera and Endoscope System

PREDICATE DEVICE

1. Device Name: Zeiss Endolive System
   Classification: Class II
   Manufacturer: Carl Zeiss, Inc.
   305 College Road East
   Princeton, New Jersey 08540
   510(k) #: K931478 and K950985

2. Device Name: Vista 3D Video Endoscope
   Classification; Class II
   Manufacturer: Vista Medical Technologies
   134 Flanders Road
   Westborough, MA 01581
   510(k) #: K970214

When compared to the predicate devices, the Vista StereoScope System 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 StereoScope System is a device used to allow observation in body cavities, organs, or canals through manmade or natural orifices. It is designed for use in all types of endoscopic and endoscopic assisted procedures. The system will be supplied as a Vista StereoScope Camera Head, Vista Stereo Endoscope and a 3D Camera Control Unit (CCU). The device is designed to work with commercially available light sources and video monitors or head mounted displays.

## INTENDED USE

The Vista StereoScope System is intended for use in endoscopic procedures and all types of video assisted procedures, including general endoscopic and laparoscopic, thoracic, anterior and posterior spinal and as an aid in visualization of cardiac structures.

## PERFORMANCE DATA

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

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|---|---|
| IEC 601-1 | General Safety Requirements for Medical Electronic Equipment |
| IEC 601-1-2 | Electromagnetic Compatibility Requirements and Tests |
| IEC 601-2-18 | Safety of Endoscopic Equipment |
| UL 2601-1 | Standard for Safety, Medical Electrical Equipment, Part 1: General Requirements for Safety |
| ISO 10993 | Biological Evaluation of Medical Devices |

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 19 1999

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

Re: K990635
Trade Name: Vista Stereoscope System
Regulatory Class: II
Product Code: GCJ
Dated: February 25, 1999
Received: February 26, 1999

Dear Ms. Anastasi:

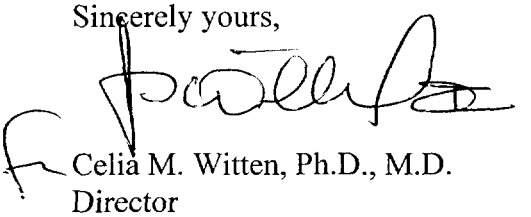
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 K990635

Device Name: Vista StereoScope System

Indications for Use:

The Vista StereoScope System is intended for use in endoscopic procedures and all types of video assisted procedures, including general endoscopic and laparoscopic, thoracic, anterior and posterior spinal and as an aid in visualization of cardiac structures.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990635

Prescription Use X or Over-The-Counter Use ____
(Per 21 CFR 801.109)