Vista Medical Technologies
Westborough MA

MAY 20 1997

510(K) SUMMARY
April 1997

COMPANY NAME AND ADDRESS

Vista Medical Technologies
134 Flanders Road
Westborough, MA. 01581

CONTACT PERSON

Martin Newman
Director of Regulatory Affairs and Quality Assurance
Telephone (508) 366-3668
Fax: (508) 366-1543

DEVICE TRADE NAME

Vista Single Chip Video Camera System

COMMON NAME

Video Camera System

PREDICATE DEVICE

1.	Device Name:	Oktas
	Classification:	Endoscopes and Accessories - 21 CFR 876.1500
	Manufacturer:	Oktas 134 Flanders Rd Westborough, MA 01581
	510(k) #:	K946171
2.	Device Name:	Olympus OTV-S5 Video System
	Classification:	Endoscope and Accessories
	Manufacturer:	Olympus Endoscope Division Two Corporate Center Drive Melville, New York 11747-3157
	510(k) #:	K955404

When compared to the predicate devices, the Vista Single Chip Video Camera 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 Single Chip Video Camera 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 product is a video camera. The system will be supplied as a Vista Single Chip Video Camera Head and a Camera Control Unit (CCU). The device is designed to work with commercially available light sources, V&C mount endoscope couplers and video monitors or head mounted displays.

INTENDED USE

The device is intended for use in all types of endoscopic and endoscopic assisted procedures.

PERFORMANCE DATA

The Vista Single Chip Video Camera was designed and will be tested in compliance with the requirements of the following standards:

IEC 601-1	General Safety Requirements for Medical Electronic Equipment
IEC 601-1-2	Electromagnetic Compatibility Requirements and Tests
UL544	Standard for Safety Medical and Dental Equipment
	Optical Test Data

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 1997

Mr. Martin Newman
Director of Regulatory Affairs and
Quality Assurance
Vista Medical Technologies, Inc.
134 Flanders Road
Westborough, Massachusetts 01581

Re: K971373
Vista Single Chip Video Camera System
Dated: May 8, 1997
Received: May 9, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 KOG

Dear Mr. Newman:

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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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) 594-4616. 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971373

Device Name: Vista Single Chip Video Camera System

Indications for Use:

The Vista Single Chip Camera System is intended for use with optical endoscopes to provide a video image of the target area.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert P. Nalling

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K971373

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

(Optional Format 1-2-96)