

APR 14 1997

Vista Medical Technologies
Westborough MA

510K Notification
Vista Mini Cameras
January 1997

K970369

510(K) SUMMARY
January 1997

COMPANY NAME AND ADDRESS

Vista Medical Technologies
134 Flanders Road
Westborough, MA. 01581

CONTACT PERSON

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DEVICE TRADE NAME

Vista Mini Camera(s)

COMMON NAME

Video Endoscope System

PREDICATE DEVICE

1. Device Name: 3D Scope Three Dimensional Medical VideoSystem
Classification: Camera, Television, Endoscopic, without audio
Manufacturer: American Surgical Technologies
300 Billerica Rd
Chelmsford, MA 01824
510(k) #: K923160, K961182
2. Device Name: Oktas Video Endoscope System with Zoom
Classification: Endoscopes and Accessories -
21 CFR 876.1500
Manufacturer: Oktas
134 Flanders Rd
Westborough, MA 01581
510(k) #: K946171

3. Device Name: Zeiss EndoLive™ Stereo Endoscope
 Classification: Endoscopes and Accessories -
 21 CFR 876.1500
 Manufacturer: Carl Zeiss, Inc.
 Thornwood, NY 10594
 510(k) #: K950988

DEVICE DESCRIPTION

The Vista Mini Camera 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 endoscopic procedures and all types of video assisted procedures, including anterior spinal and general thoracic procedures and as an aid in visualization of the evacuated cardiac chamber. The product is a video camera. The system will be supplied as a Vista Mini Camera, intended to be used with a Vista 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 device is intended for use in endoscopic procedures and all types of video assisted procedures, including anterior spinal and general thoracic procedures and as an aid in visualization of the evacuated cardiac chamber.

PERFORMANCE DATA

The Vista Mini Camera System was designed and 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
IEC 601-2-18	Safety of Endoscopic Equipment
ISO 10993	Biological Evaluation of Medical Devices
UL544	Standard for Safety, Medical and Dental Equipment
	Optical Test Data