

Vista Medical Technologies  
Westborough, MA

510(k) Notification  
Illumination System  
January 1997

K 970217

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510(k) SUMMARY  
January, 1997

COMPANY NAME AND ADDRESS

Vista Medical Technologies  
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Westborough, MA 01581

CONTACT PERSON

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DEVICE TRADE NAME

Vista Illumination System

COMMON NAME

Xenon Light Source for Endoscopic Procedures

PREDICATE DEVICE

Device Name: Cogent Light Illuminator 10010 Xenon Light Source and  
Fiberoptic Cable  
Classification: Illuminator, Fiberoptic for Endoscope  
Manufacturer: Cogent Light Technologies, Inc.  
650 S. San Vicente Blvd.  
Los Angeles, CA 90048-4620  
510(k)#: K933405

## DEVICE DESCRIPTION

The Vista Illumination System, is a Xenon Light Source illumination system consisting of a light source unit which houses the lamp and a fiberoptic cable. The system provides visible light for illumination of rigid or flexible endoscopes, laparoscopes, video cameras, headlamps, etc.

The light source has 2 ports which are provided with independent attenuator controls and separate light output intensity level indicators. The front panel contains dual intensity level indicators as well as system fault and lamp fault LED's. The LED's will light if the lamp fails to start or fails during use for any reason. There is a LCD on the front panel that provides an indication of lamp life.

The fiberoptic cable produces a uniform beam profile from a single fiber. There are three different adapters to allow connection to various endoscopic devices currently available. The thread types are for Storz, ACMI and Wolfe. Custom adapters are available. The fiber is available in core diameter of 0.1mm to 1mm with a standard cable length of 10 feet.

## INTENDED USE

The Vista Illumination System is intended to provide visible light for illumination of various rigid and flexible endoscopes, laparoscopes, cameras, and headlamps, etc. It is intended for use in all types of endoscopic and endoscopic assisted procedures, as well as visualization of the evacuated cardiac chamber.

## PERFORMANCE DATA

IEC 601-1	"General Safety Requirements for Medical Electrical Equipment"
IEC 601-1-2	"Electrical Magnetic Compatability"
UL 544	"Standards for Safety, Medical and Dental Equipment"