MAR 2 1 2000

K000 229

Appendix 5

Summary of Safety and Effectiveness

Submitter:	VideoLabs, Inc. 5960 Golden Hills Drive Minneapolis, MN 55416 Telephone: (612) 542-0061	
Product:	Classification Name:	Endoscopic Accessories (21 CFR 876.1500)
	Common Name:	Video Camera and Light Source
	Trade/Proprietary Name:	MedCam® ProPlus Video Camera and Integrated Light Source
Substantially Equivalent Products	AngioLaz (K933868), Welch Allyn VDX-300 Imaging and Illumination Platform (K no. unknown) and other commercially distributed devices.	
Description:	The VideoLabs Inc. MedCam ProPlus video camera and integral light source system consists of a video camera, base unit with integral light source and fiber optic light cable.	
Intended Use	This system illuminates the operative site and provides video images of it that can be displayed on a monitor. It is designed for attachment to endoscopes, laparascopes and arthroscopes that are used for surgical procedures.	
Comparison To Substantially Equivalent Products:	Predicate devices have the same intended use, designs and principle of operation. Differences between the new and predicate devices were subjected to optical, electrical safety and firmware testing to demonstrate that they do not affect safety and effectiveness.	

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 21 2000

VideoLabs, Inc.
c/o Mr. Frank B. Freedman
Alliancz Medical Consultants, Inc.
2530 Pennsylvania Avenue
Saint Louis Park, MN 55426

Re: K000229
VideoLabs® MedCam® ProPlus Video Camera and Integrated Light Source
Dated: January 19, 2000
Received: January 27, 2000
Regulatory Class: II
21 CFR §876.1500/Procode: 78 KOG and FCW

Dear Mr. Freedman:

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 legally marketed predicate 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 requirements, 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) 594-4591. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

Daniel G. Schultz, M.D.
Captain, USPHS
Director, Division of Reproductive, Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

510(k) Number (if known): K000229

Device Name: VideoLabs MedCam ProPlus Video Camera and Integrated Light Source

Indications For Use:

The MedCam ProPlus Video Camera and Integrated Light Source illuminate the operative site and provide video images of it that can be displayed on a monitor. It is designed for attachment to endoscopes, laparascopes and arthroscopes that are used for surgical procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K000229