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510(k) SUMMARY
February 10, 1997

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

Submitter's Name and Address: **akos** biomedical, inc.
Contact Person: Lacyne Avery
Trade or Proprietary Name: To Be Determined
Common Name: Endoscope
Classification Name: Endoscope
Device Class: Class II, within the Division of Gastroenterology-Urology Devices,
Regulation Number: 21CFR Part 876.1500 Procode: 78KOG

Indications for Use: The endoscope system is used to examine body cavities, hollow organs and canals, specifically the lower GI tract (colon) only, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

Device Description: The endoscope system includes the endoscope with control head, a disposable assembly, an imaging system, and a fluid and air system. The endoscope system features: 1) a smooth control head containing a minimal number of outside angles and joint crevices, 2) a single use disposable system encompassing all of the inner passage channels that start at the manifold, continue through the endoscope cavity, and seal onto the outside of the rigid distal tip, 3) a pneumatically driven air and fluid system eliminating the need for mechanical valves in the contamination path, and 4) a lavage function that provides a bolus of water through the working channel to loosen and flush debris from the field of view as the insertion tube advances through the colon.

Predicate Device 510(k) Information:

Company Name	510 (k) No.	510(k) Description per CDRH Electronic Docket
Olympus Corporation	K853585	Olympus EVS-Endoscopic Video Image & Data Sys.
Pentax Precision Inst.	K951576	FS-34P2, Fiber Sigmoidoscope
	K951577	ES-3800, Video Sigmoidoscope
	K951579	EC-3800TL, Video Colonoscope
	K951574	EC-3800L, Video Colonoscope
Vision Sciences, Inc.	K932843	Flexible Video Sigmoidoscope System w/Disp. Sheath
	K933247	Protective Sheath - Flexible Nasopharyngo-Larygnoscope
	K921690	Flexible Fiberoptic Sigmoidoscope System
	K921244	Disposable Protective Sheath
Fujinon, Inc.	K944759	200 Series Gastro-Intestinal Video System
	K933906	Choledochoscope/Endoscope Modification
Welch Allyn, Inc.	K954704	VS-200 Video Sigmoidoscope
	K950429	Video Sigmoidoscope
	K801247	CCD Endoscope

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Sterilization: The Disposable Assembly will be marketed as "Sterile" - "Contents Are Sterile If Package Is Unopened and Undamaged", it will NOT be labeled as "pyrogen free." Sterilization with a SAL of 10-6 is to be performed by E-Beam radiation at TITAN Scan Systems, San Diego, California, using "Method 1" as defined in the ANSI/AAMI/ISO 11137-1994 "Sterilization of health care products - Requirements for validation and routine control - Radiation sterilization."

Safety Performance Specification / Standards (Applicable Sections):

FCC	47 CFR Parts 0 to 19 (Part 18 is the applicable section)
UL 94	Tests for Flammability of Plastic Materials for Parts in Devices and Appliances
UL 1572	High Intensity Discharge Lighting Fixtures
UL 2601-1	Medical Electrical Equipment, Part 1: General Requirements for Safety
CSA	C22.2 No. 0.4-M1982 Bonding and Grounding of Electrical Equipment
CSA	C22.2 No. 601.1 Medical Electrical Equipment, General Requirements for Safety
G95-1	FDA Blue Book Memo - Required Biocompatibility Training and Toxicology Profiles for Evaluation of Medical Devices
U.S.P.	United States Pharmacopeia - Table 1. Classification of Plastics
ISO10993-1R	Biological Evaluation of Medical Devices, Part 1: Evaluation and Testing
ISO 11137	Sterilization of Health Care Products, Requirements for Validation and Routine Control, Radiation Sterilization.
IEC 320-1	Appliance Couplers for Household and Similar General Purposes
IEC 601-1	Medical Electrical Equipment, Part 1: General Requirements
IEC 601-1-1	Medical Electrical Equipment, Part 1: General Requirements for Safety Collateral Standard: Safety Requirements for Medical Electrical Systems
IEC 601-1-2	Medical Electrical Equipment, Part 1: General Requirements for Safety Collateral Standard: Electromagnetic Compatibility - Requirements and Tests
IEC 601-2-18	Medical Electrical Equipment, Part 2: Particular Requirements for the Safety of Endoscopic Equipment
IEC 801-1	Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment, Part 1: General Introduction
IEC 801-5	Electromagnetic Compatibility for Industrial-Process Measurement and Control Equipment, Part 5: Surge Immunity Requirements
IEC 1000-4-2	Electromagnetic Compatibility (EMC), Part 4: Testing and Measurement Techniques, Section 2: Electrostatic Discharge Immunity Test Basic EMC Publication
IEC 1000-4-3	Electromagnetic Compatibility (EMC), Part 4: Testing and Measurement Techniques, Section 3: Radiated, Radio-Frequency, Electromagnetic Field Immunity Test
IEC 1000-4-4	Electromagnetic Compatibility (EMC)
EN 50082-1	Generic Immunity Standard for a Light Industrial Environment
EN 55011	Limits and Methods of Measurement of Electromagnetic Disturbance Characteristics of Industrial, Scientific and Medical (ISM) Radio Frequency Equipment CISPR 11
EN 60950	Safety of Information Technology Equipment Including Electrical Business Equipment
4169-94	ASTM Standard Practice for Performance Testing of Shipping Containers and Systems

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TABLE OF COMPARISONS TO PREDICATE DEVICES

	akos (TBD)	akos (TBD)	Olympus CF-100S	Olympus CF-130S	Olympus E-GIF	Olympus E-CF	Pentax FS-34P2	Pentax ES-3801	Pentax EC-3801S2	Pentax EC-3400M
Viewing Direction	Forward	Forward	Forward	Forward	Forward	Forward				
Optical Field of View	135degrees	125degrees	140degrees	140degrees	113degrees	133degrees	120degrees	120degrees	120degrees	120degrees
Optical Depth of Field	5-100mm	5-100mm	5-100mm	5-100mm	8-65mm	7-60mm	3-100mm	5-100mm	5-100mm	5-100mm
Rigid Tip Diameter	13.7mm	14.2mm	15.4mm	13.2mm	11.4mm	15.4mm	11.5mm	13.4mm	13.4mm	13.0mm
Bending Tip Deflection	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	210up/90dn&100r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left
Bending OD	13.4mm	14mm			11.2mm	13.8mm				
Insertion Tube Dia.	13.2mm	13.9mm	13.3mm	13.3mm	11.4mm	13.8mm	11.5mm	12.8mm	12.8mm	11.5mm
Insert. Working Length	700mm	1750mm	620mm	640mm	1025mm	I:1330 / L:1680mm	700mm	700mm	1150mm	1300mm
Biopsy Channel ID	3.2mm	3.8mm	3.2mm	3.2mm	2.8mm	3.2mm	3.5mm			
Total Length	1020mm	2070mm	920mm	935mm			1015mm	1020mm	1470mm	1620mm
Op. Env. Amb. Temp	12-35deg C	12-35deg C	10-40deg C	10-40deg C						
Op. Env. R Humidity	15-85 %	15-85 %	30-85 %	30-85 %						
Atmospheric Pressure	70-106kPa	70-106kPa	700-1060mbars	70-106kPa						
Disposable Channels	Yes	Yes	No	No	No	No	No	No	No	No

	Vision Sci. VSI2000	Vision Sci. S-F100	Fujinon COL-ST2/LT2	Fujinon SIG-ET2	Fujinon COL-MP/LP2	Fujinon SIG-GP	Fujinon EC7-MR/LR2	Fujinon ES7-ER2	Fujinon EC7-MT/LT2	Welch Allyn FX-100
Viewing Direction	Forward	Forward	Forward	Forward	Forward	Forward	Forward	Forward	Forward	Forward
Optical Field of View	120degrees	120degrees	110degrees	110degrees	105degrees	105degrees	125degrees	125degrees	125degrees	100degrees
Optical Depth of Field		3-100mm	4-120mm observation	4-120mm observ.	4-120mm observ.	3-100mm observ.	5-100mm observ.	5-100mm observ.	5-100mm observ.	3-100mm focal
Rigid Tip Diameter		13.8mm	14.0mm	14.0mm	11.5mm	11.8mm	13.0mm	13.0mm	14.3mm	
Bending Tip Deflection	180up/dn 160r/left	180up/dn 150r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left	180up/dn 160r/left
Bending OD			14.0mm	14.0mm	11.5mm	11.8mm	13.0mm	13.0mm	14.0mm	
Insertion Tube Dia.	12.8mm	12.8mm								13.5mm
Insert. Working Length	65cm	65cm	1010-1735mm	765mm	1475-1735	650mm	1520-1770mm	790mm	1520-1770mm	65cm
Biopsy Channel ID	3.2mm	3.2mm	4.3mm	4.3mm	3.2mm	3.2mm	3.2mm	3.2mm	4.3mm	3.2mm
Total Length			1265-1990mm	1020mm	1730-1990mm	980mm	1850-2100mm	1120mm	1850-2100mm	
Op. Env. Amb. Temp										
Op. Env. R Humidity										
Atmospheric Pressure										
Disposable Channels	Yes	Yes	No	No	No	No	No	No	No	No

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 27 1997

Ms. Lacyne Y. Avery
Director, Quality Assurance
and Regulatory Affairs
Akos Biomedical, Inc.
6450 Lusk Boulevard, Suite 109
San Diego, California 92121

Re: K964131
Video Endoscope System
Dated: April 11, 1997
Received: April 14, 1997
Regulatory class: II
21 CFR §876.1500/Product code: 78 FAM and FDF

Dear Ms. Avery:

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): K964131

Device Name: Video Endoscope System

Indications For Use:

The akos endoscope system is used to examine body cavities, hollow organs and canals, specifically the lower GI tract (colon) only, and, using additional accessories, to perform various diagnostic and therapeutic procedures.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Robert R Saltzman

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K964131

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

(Optional Format 1-2-96)