K033870

"510(k) SUMMARY"
Summary of Safety and Effectiveness

MAR 1 2 2004

Submitter's Name & Address: Welch Allyn Inc.
4341 State Street Road
Skaneateles Falls, New York 13153

Contact Person & Telephone: David Klementowski
(315) 685-4133

Date Summary Prepared: September 22, 2003

Device Name: Classification Name - Medical Image Digitizer
Common/Usual Name – Image Management System
Proprietary Name – Image Management System

Predicate Device: Chili Video, Chili VideoPro (510(k) number K000411)

Device Description:

The Welch Allyn Image Management System is intended for use with the Welch Allyn video colposcope. The Welch Allyn video colposcope was approved under 510(k) number K955635.

This system enables a customer to save an image to the customer's electronic file system for future reference and also allows the customer to review images based on patient identifier and visit date. The file image may be imported into or linked to a patient record in an electronic medical record/electronic health record if desired.

The third-party DV Converter attaches to the Welch Allyn Colposcope through an SVideo connection. The Colposcope produces video that the Converter accepts through the SVideo interface. The Converter digitizes the image and sends it to the PC over an IEEE 1394B connection. The IEEE 1394B connection supplies 30 frames/sec with a sampling frequency of 48kHz/16bit/2ch. Minimum customer PC system requirements to run the software will be specified.

The images captured, displayed, saved, exported, and printed from the Basic Image Management system are not intended for diagnostic purposes. The provider shall use the image on the colposcope monitor for clinical diagnosis.

Technological Characteristics:

Table 1
Predicate device feature and specification comparison:

Technological Specification	Welch Allyn Image Management System	Chili Video, Chili VideoPro
Intended Use:	Capture, display, export, and print images obtained from the Welch Allyn video colposcope.	Provide the user with a means to capture and digitize image data from a video data stream.
Used to grab images from modalities that do not have digital export functions?	Yes – from Welch Allyn colposcope	Yes
Can grab single images	Yes	Yes
Can grab sequences of images	Yes	Yes
Operated by computer keyboard	Yes	Yes
Operated by an external device	Yes – Welch Allyn video colposcope	No
Single channel color acquisition	N/A	Yes
Multi-channel monochrome images	N/A	Yes
Various frame grabber boards available	No	Yes
Grabbed image can be manipulated	No	No
Images can be added to a study	N/A	Yes
User enter patient demographic data	No	Yes
Images can be stored with demographic data	No	Yes
Can be used with any device that has video data stream output	Yes – but labeling indicates it is for use with Welch Allyn video colposcope	Yes
User selectable video sources	Yes – but labeling indicates it is for use with Welch Allyn video colposcope	Yes

Summary of Safety:

This system is safe for both the patient and user. The system is intended to capture, display, save, export, and print images obtained from the Welch Allyn video colposcope. The images captured, displayed, saved, exported, and printed from the Basic Image Management system are not intended for diagnostic purposes. The provider shall use the image on the colposcope monitor for clinical diagnosis.

Summary of Effectiveness:

The Welch Allyn Image Management System is effective for its intended use. Testing and evaluation indicate that the system meets the needs of the users of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2 2004

Mr. David Klementowski
Sr. Manager, Regulatory Affairs
Welch Allyn, Inc.
4341 State Street Road
P.O. Box 220
SKANEATELES FALLS NY 13153-0220

Re: K033870
Trade/Device Name: Basic Image Management System
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulation Number: 21 CFR 892.2030
Regulation Name: Medical image digitizer
Regulatory Class: II
Product Code: 85 HEX and 90 LMA
Dated: December 8, 2003
Received: December 16, 2003

Dear Mr. Klementowski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97) you may obtain. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K033870

Device Name: Basic Image Management System

Indications For Use:

The Welch Allyn Basic Image Management system is intended to capture, display, save, export, and print images obtained from the Welch Allyn video colposcope. The images captured, displayed, saved, exported, and printed from the Basic Image Management system are not intended for diagnostic purposes. The provider shall use the image on the colposcope monitor for clinical diagnosis.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use___

(Optional Format 1-2-96)

Nancy C Brogdon

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices.
510(k) Number K033870