Camtronics
MEDICAL SYSTEMS

JUL 17 2002

K021236

510(k) Summary

Date prepared: April 12, 2002

Name of contact person: Scott Pease

Device trade name: Surgery Image Recorder

Common name: Endoscope and accessories

Classification name: Endoscope and accessories

Predicate substantially equivalent devices: K011944 Dyonics Vision 635 Digital Capture System Model, Smith & Nephew, Inc.

Device description and intended use: The Surgery Image Recorder (SIR) is an acquisition unit for digitizing and storing images generated during surgical proceedings that are typically related to, but not limited to, endoscopic surgery procedures. The SIR is designed to provide surgeons the ability to capture still images and streaming video from standard video outputs typically associated with imaging devices used during endoscopic surgery. To allow for the entry of patient demographic information and to provide a user interface the SIR will have and I/O for a USB type keyboard and mouse, and will also provide I/O's for a USB compatible color printer, video outputs, serial outputs and network connectivity. Additionally, the SIR will be able to store data to its internal hard disk drive and to removable storage media (e.g., DVD, CD-R).

Predicate device specifications comparison:

	Principal Device **Camtronics Medical Systems** **Surgery Image Recorder (SIR)**	*Predicate Device* **Smith & Nephew, Inc.** **Dyonics Vision 635 Digital Capture System Model (K011944)**
Computer/operating system	PC Based hardware and operating system	PC Based hardware and operating system
User interface	PC-type Mini-keyboard	Keyboard; optional footswitch
Video input	RGB, YC, or composite input	RGB; S-Video, AUX Input
Video output	RGBS via DB9; S-Video via 4 pin DIN; VGA via DB15	RGB; S-Video
Video format	Interlaced NTSC/PAL video	NTSC and PAL
Compression type and ratio	JPEG and MPEG4	MPEG1 and MPEG2
Storage Devices	Internal hard drive; CD/DVD Recorder/Reader	Internal hard drive; CD-R; ZIP™ disk
Output capabilities	Fast Ethernet; DICOM	Fast Ethernet; DICOM

Performance data: Not required for determination of substantial equivalence for this class of device.

Conclusions drawn from clinical and nonclinical test data: Not required for determination of substantial equivalence for this class of device.

Substantial equivalence summary: The Camtronics Surgery Image Recorder (SIR) is comparable type and substantially equivalent to a legally marketed predicate device. The intended use of the Camtronics is the same as that of the predicate device "Dyonics Vision 635 Digital Capture System" marketed by Smith &b Nephew, Inc... No new safety or effectiveness issues are raised with the Camtronics SIR. The subject device has substantially equivalent technological characteristics, features, specifications, materials, modes of operation, and intended uses as a legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 17 2002

Camtronics, Ltd.
Scott Pease
Director, Quality Assurance and Regulatory Affairs
900 Walnut Ridge Drive, P. O. Box 950
Hartland, Wisconsin 53029

Re: K021236
Trade Name: Surgery Image Recorder
Regulatory Class: II
Product Code: LLZ
Dated: April 12, 2002
Received: April 18, 2002

Dear Mr. Pease:

We have reviewed your Section 510(k) premarket 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) 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. 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). 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,

for Mark N Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/ 3 - 4/24/96

Applicant: Camtronics Medical Systems

510(k) Number (if known): K021236

Device Name: Surgery Image Recorder

Indications For Use:

Acquisition unit for digitizing and storing images generated during surgical proceedings that are typically related to, but not limited to, endoscopic surgery procedures.

for Mark N Melkerson

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K021236

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Per 21 CFR 801.109)

(Optional Format 1-2-96)