SEP 1 9 2001

SECTION B: ADMINISTRATIVE INFORMATION

1. **510(k) Summary**
   Dyonics Vision 635 Digital Capture System
   Date Prepared:

K011944

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

A. Submitter

Smith & Nephew, Inc.
Endoscopy Division
160 Dascomb Road
Andover, MA 01810

B. Company Contact

Steven Jackson
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Endoscopy Division
3600 NW 138th St.
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C. Device Name

Trade Name: Dyonics Vision 635 Digital Capture System
Common Name: Picture Archiving and Communications System (PACS)
Classification Name: Image Processing System
Classification: Class II, per 21 CFR 892.2050
Product Code: LLZ

D. Predicate Device

Fotomaster™
Hamilton Thorn Research
100 Cummings Center
Suite 102-C
Beverly, MA 01915

Substantial Equivalence - K000380, May 3, 2000

E. Description of Device

The Dyonics Vision 635 Digital Capture System (DV 635) is designed to provide surgeons the ability to capture still images and motion video during surgical procedures in various file formats for archival and presentation purposes. The DV 635 connects to any device with standard video outputs via standard video connections, and provides video throughput to video monitors, and other video peripheral devices. The DV 635 utilizes an external keyboard for input of basic patient and case

information, and to set the system configuration. To capture images, the DV 635 utilizes user inputs from front panel switches, camera head buttons, the keyboard or optional footswitch. Images and motion video clips are stored on an internal hard disk drive, and later transferred to a removable storage media, including CD-R and ZIP™ disks, or to an network drive or printer via a Ethernet connection. The DV 635 may also print images directly to a postscript printer via a print server.

F. Intended Use

The Dyonics Vision 635 Digital Capture System is used in the operating room to digitally capture intra-operative still and motion images using the camera head, the foot switch, the front panel of the capture unit or the keyboard. Images are then stored in one of several standard image file formats on transportable media or to an Ethernet network for long term archival, retrieval or printing using third party image application software.

G. Comparison of Technological Characteristics

The Dyonics Vision 635 Digital Capture System (DV 635) is equivalent to the Hamilton Thorn Research Fotomaster™ in that both process, digitize, store, and save images obtained during surgical procedures using remote triggers and use standard publicly available JPEG image compression algorithms from the independent JPEG Group's software library.

The DV 635 can also store generate images in bitmap, DICOM and postscript formats, and motion video clips MPEG1 and MPEG2 formats . The DV 635 can also connect directly to a network via an Ethernet connection and download stored images to a network storage device or networked printer or may be connected to a local printer via a local print server. These changes do not impact the safety or efficacy of the device.

Steve Jack 6-20-01

Steven Jackson
Manager, Regulatory Affairs

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 9 2001

Mr. Steven Jackson
Manager, Regulatory Affairs
Smith & Nephew, Inc.
Endoscopy Division
3600 NW 138th Street
Oklahoma City, Oklahoma 73134

Re: K011944
Trade/Device Name: Dyonics Vision 635 Digital Capture System
Regulation Number: 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: GCJ
Dated: June 20, 2001
Received: June 21, 2001

Dear Mr. Jackson:

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 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,

Susan Walkowski

for 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

FDA INSTRUCTIONS FOR USE FORM

510(k) Number : Unknown K011944

Device Name : Dyonics Vision 635 Digital Capture System

Indications for Use :

The Dyonics Vision 635 Digital Capture System is indicated to be used in the operating room to digitally capture intra-operative still and motion images using the camera head, the foot switch, the front panel of the capture unit or the keyboard. Images are then stored in one of several standard image file formats on transportable media or to an Ethernet network for long term archival, retrieval or printing using third party image application software.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K011944

(Optional Format 3-10-98)