image maker

SEP 16 2003

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Food and Drug Administration
Center for Devices & Radiological Health
Office of device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, MD 20850
Etats Unis

Re: 510(k) Submission for SOPRO 61D camera
VIA UPS EXPRESS

Marseille, May 19, 2003

Dear Document Control Clerk,

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

FDA/CDRH/OSE/PRO

A. Submitter
SOPRO
Place Saint Christophe - Les Accates
F-13011 Marseille FRANCE
Phone : 33 (0) 4 91 27 07 27
Fax : 33 (0) 4 91 43 26 75

B. Company Contact
Pierre MONTILLOT
C.E.O.

C. Device Name

Trade Name :	SOPRO 61D
Classification Name	Laparoscope and Accessories, General & Plastic Surgery

D. Predicate Device
The predicate devices for this submission are the existing line of Smith & Nephew Dyonics cameras for which the 510 (k) number K936071 was granted.

E. Description Device and Technological characteristics
The SOPRO 61D is a high resolution, digital processing camera system utilizing a CCD image sensor. It provides high quality images with excellent resolution and colour contrast. This makes the camera a multidiciplinary tool.

SOPRO
ACTEON group

F. Intended Use

"Provide access, illumination and allow observation or manipulation of body cavities, hollow organs and canals. The device(s) consist of various rigid or flexible instruments inserted into these spaces and includes an optical system for conveying an image to the users eye and their accessories may assist in gaining access or increase the versatility and augment the capabilities of the device".

G. Substantial equivalence

This product is virtually identical to the SOPRO 51D camera for which a 510(k) N° K000424 was already granted. It is also virtually identical to many camera systems on the market today with respect to intended use, composition, safety and effectiveness. We cite Dyonics as device of comparison. This one, and other similar devices are virtually identical devices with the same intended uses.

Please examine the Table of Contents for a listing of the necessary components of this 510(k) filing.

We would appreciate your earliest attention to this matter. All required information is contained within, however, should any information not be totally clear or unreadable, please advise us immediatly.

Sincerely,

Pierre MONTILLOT
C.E.O.
SOPRO

Enclosures

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 6 2003

Mr. Pierre MONTILLOT
SOPRO
Place St. Christophe
Les Accates-La Valentine
Marseille
France F-13011

Re: K031593
Trade/Device Name: SOPRO 61D
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: II
Product Code: GCJ
Dated: May 19, 2003
Received: July 14, 2003

Dear: Mr. MONTILLOT:

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 (301) 594-4659. 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 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,

Miriam C. Provost

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

510(k) Number (if known): K031593

Device Name: SCOPE 610 Digital Endoscopy Camera

Indications For Use:

"Providing access, illumination and allow observation or manipulation of body cavities, hollow organs and canals."

(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 ___
(Per 21 CFR 801.109)

Miriam C. Provost (Optional Format 1-2-96)
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K031593