

9. Summary of Safety and Effectiveness – “510(k) Summary”

A. Submitter Information

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FRANCE

APR -1 2009

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Contact Person: Rick Rosati

SOPRO
c/o ACTEON, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054
Tel: 800 289-6367 Ext. 37
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E-mail: rick.rosati@us.acteongroup.com

Date Prepared: September 22, 2008

B. Device Identification

Classification Name: Laparoscope, General & Plastic Surgery

Common Usual Name: Laparoscope and accessories

Proprietary Name: SOPRO 184 camera

C. Identification of Predicate Device

<u>Device</u>	<u>Applicant</u>	<u>510(k) No.</u>	<u>Date Cleared</u>
SOPRO 162	SOPRO	K070102	February 20, 2007

The SOPRO 184 is substantially equivalent to the predicate device by SOPRO, the SOPRO 162 (K070102) previously cleared by the FDA and currently marketed.

D. Device Description

The SOPRO 184 is a high resolution, digital processing camera system utilizing a CCD image sensor. It provides high quality images with excellent resolution and color contrast. Its contour enhancer gives the impression of a 3D image. This makes the camera a multidisciplinary tool.

The SOPRO 184 is a modification of the SOPRO 162 previously cleared on 510(k) K031593. The modifications are the addition of RGBS & USB2 outputs, 2 SDI outputs as an option and the modification of the head design for the ergonomic.

E. Intended Use

The SOPRO 184 providing access, illumination and allow observation or manipulation of body cavities, hollow organs, and canals.

F. Substantial Equivalence

The SOPRO 184 camera and the predicate device, SOPRO 162 camera (K070102) are both laparoscopes and accessories for use in general and plastic surgery by qualified physicians. Differences that exist between the devices relating to technical specifications, performances and intended use are minor and do not affect the safety and effectiveness of the SOPRO 184.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 1 2009

Sopro
% Acteon, Inc.
Mr. Rick Rosati
124 Gaither Drive, Suite 140
Mount Laurel, New Jersey 08054

Re: K082796
Trade/Device Name: SOPRO 184 Digital Endoscopy Camera
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: March 9, 2009
Received: March 11, 2009

Dear Mr. Rosati:

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.

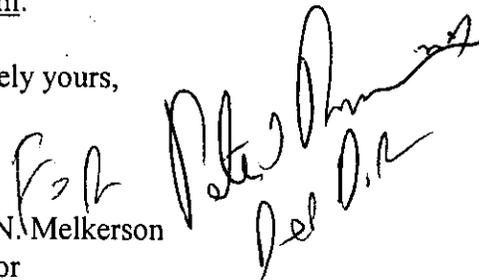
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', is written over the typed name and title.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K082796

Device Name: **SOPRO 184 Digital Endoscopy Camera**

Indications for Use:

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

Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krome for MVM 3/3/09

(Division Sign-Off)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K082796