K072912

8. Summary of Safety and Effectiveness – "510(k) Summary"

A. Submitter Information

SOPRO
ZAC Athélia
Avenue des Genévriers
13705 La Ciotat Cedex
FRANCE

Telephone: 33 (0) 442 98 01 01
Fax: 33 (0) 442 71 76 90

NOV 16 2007

Contact Person: Steve Salesky
SOPRO
c/o ACTEON, Inc.
124 Gaither Drive, Suite 140
Mt. Laurel, NJ 08054
Tel: 800 289-6367 Ext. 40
Fax: 856 222-4726
E-mail: steve.salesky@us.acteongroup.com

Date Prepared: October 11, 2007

B. Device Identification

Classification Name: Laparoscope, General & Plastic Surgery

Common Usual Name: Laparoscope and accessories

Proprietary Name: SOPRO 225 Dual halogen light source

C. Identification of Predicate Device

Device	Applicant	510(k) No.	Date Cleared
WOLF LP 4251	Richard Wolf Medical Instruments Corp.	K010033	January 10, 2002

The SOPRO 225 is substantially equivalent to the predicate device by the Richard Wolf Instruments Corporation, the WOLF LP 4251 (K010033) previously cleared by the FDA and currently marketed.

D. Device Description

The SOPRO 225 is a light source with two 250W Halogen reflector lamps, mechanical iris light intensity control, and connections for fiber optic light cable. A switch on the front panel provides for lamp selection.

E. Intended Use

The SOPRO 225 Dual halogen light source is intended to be used by qualified physicians in general and plastic surgery to provide light for examination, diagnostic and therapeutic applications, particularly in endoscopy".

F. Substantial Equivalence

The SOPRO 225 dual halogen light source and the predicate device WOLF LP 4251 dual halogen light source are both in Class II Endoscope and Accessories intended for use by qualified physicians.

The SOPRO 225 and the predicate are both dual halogen light sources intended to be used by qualified physicians in general and plastic surgery to provide light for examination, diagnostic and therapeutic applications, particularly in endoscopy".

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2007

SOPRO
% ACTEON, Inc.
Mr. Steve Salesky
124 Gaither Drive, Suite 140
Mt. Laurel, New Jersey 08054

Re: K072912
Trade/Device Name: SOPRO 225 DUAL HALOGEN LIGHT SOURCE
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: GCJ
Dated: October 11, 2007
Received: October 12, 2007

Dear Mr. Salesky:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

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: K072912

Device Name: **SOPRO 225 DUAL HALOGEN LIGHT SOURCE**

Indications for Use:

"Provides light for examination, diagnostic and therapeutic applications, particularly in endoscopy"

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)

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

510(k) Number K072912