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

K 103813

A. Submitter Information

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SOPRO
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Date Prepared: December 27, 2010

B. Device Identification

Classification Name: Led light source

Common/Usual Name: Endoscope and accessories

Proprietary Name: SOPRO 281

C. Identification of Predicate Device

Device	Applicant	510(k) N°	Date cleared
LO-50 LED Light Source	Fiberoptics Technology inc	K102167	08/17/2010
LLS-050	Sunoptic technologie	K093792	03/18/2010

The SOPRO 281 is substantially equivalent to the predicate devices by the Fiberoptics Technology inc ,LO-50 LED Light Source, or Sunoptic technologie LLS-050 previously cleared by the FDA and currently marketed.

D. Device Description

The SOPRO 281 is a light source with one led lamp, electronic iris light intensity control, and connections for a fiber optic light cable. A switch on the top of the device enables light output and intensity control. A multi-color led indicates device status

E. Intended Use

The SOPRO S281 LED light source is intended to be used by qualified physicians in general and plastic surgery to Provides light for examination, diagnostic and therapeutic applications, particularly in endoscopy

F. Substantial Equivalence

The SOPRO 281 LED light source is similar to the LO-50 led light source (K102167) and to LLS-050 (K093792) predicate devices in terms of technical specifications, performances, and intended use. Further the SOPRO 281 has the same properties of safety and effectiveness as the predicates.

The SOPRO 281 , LO-50 LED and LLS-050 Light Source are all LED 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
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

SOPRO
% Aceton, Inc.
Mr. Rick Rosati
124 Gaither Drive, Suite 140
Mt. Laurel, New Jersey 08054

MAR 2 2 2011

Re: K103813
Trade/Device Name: SOPRO 281 LED LIGHT SOURCE
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: NTN, FCW
Dated: December 27, 2010
Received: December 29, 2010

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); 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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for

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

Enclosure

Indications for Use

510(k) Number: K103813

Device Name: **SOPRO 281 LED LIGHT SOURCE**

Indications for Use:

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

Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (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 Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103813