DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 9, 2016

Sopro-Comeg GmbH
% Ms. Angelika Scherp
Regulatory Affairs Consultant
Business Support International
Amstel 320-1
Amsterdam, 1017AP NL

Re: K153701
Trade/Device Name: ULYSS Multi View Sinuscope
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible or Rigid) and Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: August 4, 2016
Received: August 8, 2016

Dear Ms. Scherp:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K153701

Device Name
ULYSS Multi View Sinuscope

Indications for Use *(Describe)*
The ULYSS Multi View Sinuscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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ULYSS Multi View Sinuscope

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Date:	August 29, 2016	
Submitter:	Name:	SOPRO-COMEG GmbH
	Address:	Dornierstrasse 55 78532 Tuttlingen Germany
	Contact Person:	Angelika Scherp
	Telephone:	(31) 20-612-5626
	Fax:	(31) 84-735-7788
Product:	Trade Name:	ULYSS Multi View Sinuscope
	Common Name:	Endoscope
	Classification Name:	Nasopharyngoscope (flexible or rigid) and accessories
	Regulation Number	21 CFR 874.4760
	Product Code	EOB
Predicate Device:	K132433 –Acclarent Cyclops Multi-Angle Endoscope	
Reference Device:	K944656 – Optus Sinuscopes and Accessories	
Device Description:	The ULYSS Multi View Sinuscope is a 4.3 mm rigid endoscope. The sinuscope is intended for visualization only and does not include operative channels. Instruments do not go through nor come in contact with the scope. The handle part of the ULYSS Multi View Sinuscope incorporates two rotating dials that permit o continuous adjustment of the direction of view from 10° to 100° by means of small magnets incorporated into the sinuscope body; o 340° rotation of the outer tube (from -170° to +170°). The sinuscope is provided with a rod lens system to transmit images and bundled optical fibers to transmit light from an external light source to illuminate the visual field. A light guide connector is provided for connection to an Olympus®, Storz® or Wolf® light cable by means of an appropriate adapter. The endoscope is also provided with an eyepiece that is compatible with a standard camera coupler. The ULYSS Multi View Sinuscope is a reusable device and must be cleaned and sterilized before use.	
Description of Accessories:	The following optional accessories are available for use with the ULYSS Multi View Sinuscope to provide a conduit for suction and irrigation of the operating site during surgical procedures. Both incorporate standard connections for suction and irrigation tubing. o Suction Irrigation Handle and Adaptable Tube o Suctions Irrigation Sheaths	
Indications for Use:	The ULYSS Multi View Sinuscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.	

ULYSS Multi View Sinuscope

Performance Data:

Performance testing of the ULYSS Multi View Sinuscope consisted of bench testing and a cadaver study, as summarized below:

- Thermal safety testing in accordance with IEC 60601-2-18
- Evaluation of magnetic field strength and potential effects on electronic devices in immediate vicinity of the ULYSS Multi View Sinuscope (comparison testing with predicate device)
- Optical performance comparison with predicate device at complete range of viewing directions
- Evaluation of quality, illumination, and resolution of images inside the nasal cavity in a cadaver (comparison testing with predicate device)
- Biocompatibility evaluation in accordance with ISO 10993-1

The ULYSS Multi View Sinuscope has met all specified design and performance requirements.

Reprocessing and Sterilization Testing

Reprocessing and sterilization validation testing met all acceptance criteria and has demonstrated a sterility assurance level (SAL) of 10^{-6} for sterilization via pre-vacuum steam sterilization.

Technological Characteristics

The technological and performance characteristics of the device are similar to those of the predicate devices, as shown by the following summary table:

	Subject Device	**Predicate Device**	**Reference Device**
510(k) No.	**Pending**	**K132433**	**K944656**
Device	ULYSS Multi View Sinuscope	Acclarent Cyclops Multi-Angle Endoscope	Optus Sinuscopes
Model #	161 401 760	CYE002	171.271.xxx 161.271.xxx
510(k) Sponsor	SOPRO-COMEG GmbH	ACCLARENT, Inc.	OPTUS, Inc.
Intended Use	The ULYSS Multi View Sinuscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.	The Acclarent Cyclops Multi-Angle Endoscope is intended to provide an endoscopic means to view the nasal cavity and nasopharynx.	Optus Sinuscopes are intended to be used to visualize the sinus area.
Materials	Glass, stainless steel, titanium, rare-earth permanent magnets	Glass, stainless steel, titanium, rare-earth permanent magnets	Glass, stainless steel
Rigidity	Rigid	Rigid	Rigid
Lens System	Rod-lens relay system	Achromatic relay system	Rod-lens relay system
Depth of View	2.5-45 mm	5-45 mm	2-50 mm
Field of View	60°	55°	71°-83°
Direction of View	10° to 100°	10° to 90°	0°, 30° or 70°
Rotation of Outer Tube	340°	320°	N.A.
Shaft Diameter	4.3 mm	4.3 mm	2.7 mm or 4 mm

Working Length	175 mm	175 mm	174.5 mm
Sterility	Non-sterile	Non-sterile	Non-sterile
Reusable	Yes	Yes	Yes

Conclusion: The information provided in this 510(k) submission provides reasonable assurance that the subject device ULYSS Multi View Sinuscope is safe and effective and that it is substantially equivalent to the predicate device with respect to intended use and technological characteristics.