DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 15, 2016

Gyrus ACMI, Inc.
Mr. Dolan Mills
Sr. Specialist, Regulatory Affairs
136 Turnpike Road
Southborough, MA 01772

Re: K152531
Trade/Device Name: InstaClear Lens Cleaner
Regulation Number: 21 CFR 874.4760
Regulation Name: Nasopharyngoscope (Flexible Or Rigid) And Accessories
Regulatory Class: Class II
Product Code: EOB
Dated: September 2, 2015
Received: September 3, 2015

Dear Mr. Mills:

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)*
K152531

Device Name
InstaClear Lens Cleaner

Indications for Use *(Describe)*
Intended to clear the end of a rigid rod endoscope in order to maintain clear visualization of endoscopic procedures without having to remove the scope from the surgical site.

The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary of Safety and Effectiveness
Gyrus ACMI, Inc.
InstaClear Lens Cleaner

General Information

Manufacturer and 510(k) Submitter:	Gyrus ACMI, Inc., an Olympus company 136 Turnpike Road Southborough, MA 01772-2104 Phone: 1-800-262-3540 Fax: 1-901-373-0260
Establishment Registration Number:	3003790304
Manufacturing Site:	2925 Appling Road Bartlett , TN 38113 Phone: 1-800-262-3540 Fax: 1-901-373-0260
Establishment Registration Number:	1037007
Contact Person:	Dolan Mills Senior Specialist, Regulatory Affairs
Date Prepared:	September 2, 2015

Device Description

Classification Name:	Nasopharyngoscope and Accessories
Regulatory Class	Class 2
Regulation Number	21 CFR 874.4760
Review Panel	Ear, Nose, & Throat Panel
Product Code	EOB
Project Name:	Lens Cleaner (12-016)
Trade Name(s):	InstaClear
Generic/Common Name:	Nasopharyngoscope (flexible or rigid) and accessories

Predicate Device

Medtronic Endo-scrub 2: K982594

Product Description

The InstaClear Lens Cleaner system is equivalent to the predicate device cleared under K982594. The system includes a reusable AC powered console with pump, a reusable footpedal, and sterile disposable single-use accessories.

The system is used to clear the end of a rigid endoscope in order to maintain clear visualization of endoscopic procedures without having to remove the scope from the surgical site. The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery (ESS).

The system accessories include sterile sheaths to fit various sizes of 4mm Olympus and Storz endoscopes, a sterile irrigation tubeset, and a non-sterile footpedal. The console includes software to control irrigation delivery and suction.

When performing ESS the scope is inserted into the nasal passages to visualize the sinuses. During the resection of tissue the scope lens is frequently covered in debris, such as blood and mucous that limits visualization. Traditionally the surgeon has to remove the scope, clean the lens, return the scope, and resume surgery. The proposed device is intended to attach directly to the endoscope shaft and provide fluid and suction to clean the lens of unwanted debris. This provides the surgeon with better images without debris and less instrument exchanges.

Technological Characteristics

The system is used in the same way as the predicate system (K982594). The disposable sheath is placed on the shaft of an endoscope and directs fluid to the lens of the scope for the purpose of cleaning the lens of debris. Fluid delivery is actuated by a simple footpedal. Other than the footpedal and the console there are no other capital requirements. Fluid is pressurized using a pump on the console. The flow rate may be controlled by an adjustable knob on the back of the console. Connections to the console are limited to loading the tubeset through the pump, and connecting the footpedal.

Material

The system uses the same patient-contacting materials that are utilized in predicate devices, as well as other legally marketed devices manufactured by Gyrus ACMI.

The patient contacting items are classified in accordance with ISO 10993-1, as an external communicating, tissue/bone/dentin device for limited exposure (<24hrs.). ISO

10993-1 and FDA Blue Book memo #G95-1 guidelines recommend that these direct patient contact parts have supporting data for cytotoxicity, sensitization and irritation. Full GLP biocompatibility testing (Cytotoxicity, sensitization, and irritation) on similar devices containing all patient contacting materials is on file for other devices currently marketed by Gyrus ACMI.

Intended Use / Indications

Intended to clear the end of a rigid rod endoscope in order to maintain clear visualization of endoscopic procedures without having to remove the scope from the surgical site.

The device is indicated for use during routine diagnostic procedures and during endoscopic sinus surgery.

Compliance to Standards

The design of the system complies with the following standards:

IEC 60601-1, IEC 60601-1-2, IEC 60601-2-18
ISO 10993-1, 5, 7, 10, Biological Evaluation of Medical Devices
ISO 14971, Risk Analysis
ISO 15223-1:2012, Medical Devices - Symbols to be used
ISO 11135:2014, Sterilization of Health Care Products, EO Validation
ISO 11138: 2006, Sterilization of health care products: Biological Indicators
ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices
ISO 11607-2:2006, Packaging for Terminally Sterilized Medical Devices
ISO 11737-1:2006, Sterilization of Medical Devices – Microbiological Methods
ISO 11737-2:2009, Sterilization of Medical Devices – Microbiological Methods

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971. The design verification tests were identified and performed as a result of risk analysis assessment.

Electrical safety and electromagnetic compatibility (EMC)

Electrical safety and EMC testing were conducted on the device. The device complies with the applicable clauses of IEC 60601-1, and the IEC 60601-1-2 standard for EMC.

Summary of Sterilization and Shelf Life Discussion

The system console and footpedal are provided non-sterile and are reusable. The console and footpedal are to be wiped down with cleaning / disinfecting wipes after use.

The sheaths and tubesets are provided sterile for single-use. They are sterilized with Ethylene Oxide, using a cycle validated in accordance with ISO 11135 to provide a sterility assurance level of 10^{-6}.

The Shelf Life period for the disposable items was determined through an analysis of the shelf-life stability of the materials used in the design of the devices, as well as an analysis of the packaging materials and processes used with other Gyrus ACMI devices. Shelf-life studies are on file to support an initial one year shelf life.

Summary of Performance Testing

Performance tests were executed to ensure that the system functioned as intended and met design specifications. The following non-clinical and preclinical tests and usability studies were conducted:

Non-Clinical / Preclinical Performance
Evidence of safety and effectiveness was obtained from two primary areas:

1) non-clinical (electrical, mechanical, functional) performance testing
2) preclinical (bench) evaluations and testing

Non-clinical: Basic safety and performance testing was performed in accordance with IEC standards. In addition, verification and comparison bench studies were conducted to evaluate the mechanical and functional performance. Testing included: cleaning compatibility, noise levels, heat generation, tabletop stability, burst pressure, suction strength, hub strength, torque strength, leak testing, ship testing, and baseline performance testing.

Stability: Representative samples were subjected to accelerated aging to confirm that the disposable devices maintain functionality and continues to meet specifications over time. The results of the accelerated age testing demonstrate that the device will be stable for the stated shelf-life. In addition, real time age testing will confirm the results of the accelerated age testing. Representative samples were also subjected to environmental conditioning and ship testing.

Preclinical: Evidence obtained from preclinical bench studies demonstrate that the system performs substantially equivalent to the predicate device in relevant aspects associated with cleaning cycle time, cleaning performance, clearing performance, and

leak / drip occurrence rate. For simulated use and bench testing, the selected medium was a blood analog appropriate for testing.

Testing demonstrated that the device performs as well as or better than the predicate device.

No clinical testing was conducted. The use of the device type has been documented in published literature and indicates safe and effective use for the target procedures and expected patient populations.

Substantial Equivalence

The system operates in a similar manner as the predicate device. The disposable tubeset and sheaths are similar to the predicate devices physically and in their methods of operation. The tubeset offers irrigation to the surgical site and suction away from the surgical site.

The system uses similar or same patient-contacting materials in similar quantities that are utilized in the predicate device, as well as other legally marketed devices manufactured by Gyrus ACMI.

Conclusion

The performance of the InstaClear system was compared against the known performance characteristics of the predicate device. Testing demonstrated that the performance requirements were met, and that the system exhibited comparable performance characteristics to the predicate.

In summary, the InstaClear Lens Cleaner is substantially equivalent to the predicate device and presents no new questions of safety or efficacy.