March 8, 2018

Gyrus ACMI, Inc.
Mary Anne Patella
Senior Specialist Regulatory Affairs
136 Turnpike Road
Southborough, MA 01772

Re: K180086
Trade/Device Name: Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter
Regulation Number: 21 CFR§ 876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: FGE, KNQ
Dated: January 11, 2018
Received: January 12, 2018

Dear Mary Anne Patella:

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.

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.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180086

Device Name
Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter

Indications for Use *(Describe)*
The Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheters are indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.

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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510(k) Summary
Gyrus ACMI, Inc.
Gyrus ACMI - *EZDilate 3-Stage Balloon Dilatation Catheter*

General Information

Contract Manufacturer:	Vention Medical, Inc. 261 Cedar Hill Drive Marlborough, MA 01752 Phone: 508-481-6233
Establishment Registration Number:	3004734318
510(k) Submitter:	Olympus Surgical Technologies America Gyrus ACMI, Inc. 136 Turnpike Rd. Southborough, MA 01772-2104
Establishment Registration Number:	3003790304
Contact Person:	Mary Anne Patella Senior Specialist Regulatory Affairs 508-804-2771 Maryanne.patella@olympus-osta.com
Date Prepared:	January 11, 2018

Device Description

Classification Name:	Biliary catheter and accessories Esophageal dilator
CFR citation	21 CFR 876.5010, 876.5365
Procode	FGE, KNQ
Classification	Class II
Classification Panel	Gastroenterology/Urology
Trade Name:	Gyrus ACMI – *EZDilate 3-Stage Balloon Dilatation Catheter*
Generic/Common Name:	Balloon Dilation Catheter

Predicate Devices

Gyrus ACMI – EZDilate 3-Stage Balloon Dilatation Catheter	K143609
Boston Scientific CRE Dilatation Balloon	K112994

Product Description

Both the predicate and proposed Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheters consist of a semi-compliant nylon blow molded balloon; and, a shaft that communicates a fluid passage for expansion and collapse of the balloon portion, operated by an inflation device.

Like the predicate, the EZDilate Wire Guided Balloon is designed to be used with a 0.035 in. (0.89mm) guidewire and has a wire lumen sized appropriately. Each balloon catheter is packaged with a soft tip 0.035 in. (0.89mm) guidewire pre-loaded into the guidewire lumen. The guidewire is manufactured by Lake Region Medical; and, is cleared under K935198, Gastroenterology and Urology Guidewire Modifications. All wire-guided balloons with have lengths of 5.5cm and a catheter length of 240cm.

The balloon is inflated with a 60cc inflation device, which will be sold separately. The suggested inflation device is manufactured by Atrion (K032840).

Technological Characteristics

The proposed Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter has the same intended use, design, and scientific technology as the predicate EZDilate 3-Stage Balloon Dilatation Catheter (K143609). Both devices are the same design and there were no new issues of safety or effectiveness with the proposed device.

The Gyrus ACMI EZDilate 3-StageWire Guided Balloon Dilatation Catheter is a reinforced catheter attached to a distal dilatation balloon. The semi-compliant balloon allows for a progressive radial expansion through three target sizes using one balloon. A silicone coating applied to the balloon increases ease of insertion, positioning of the balloon within the alimentary tract, and device removal.

Material

No material changes were made to the predicate EZDilate 3-Stage Balloon Dilatation Catheter cleared under K143609.

Intended Uses

The Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheters are indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.

Summary of Sterilization and Shelf Life Discussion

Like the predicate EZDilate 3-Stage Balloon Dilatation Catheter (K143609), the proposed EZDilate 3-Stage Balloon Dilatation Catheter will be distributed in a sterile state and is intended for single patient use only. The sterilization method used is ethylene oxide and has a shelf life of three (3) years.

Summary of Performance Testing

The predicate EZDilate 3-Stage Balloon Dilatation Catheter (K143609) and the proposed EZDilate 3-Stage Balloon Dilatation Catheter are identical in every respect. Minor process changes to the predicate EZDilate – Wire Guided 18-19-20 balloon catheter resulted in rounder shoulders to the balloon; enhancing balloon visualization. As a result of the process changes, the following performance tests were repeated.

- Visual Inspection
- Dimensional Measurements
- Tensile Testing
- Fatigue Testing
- Luer Gauging Test
- Balloon Working Length
- Tip Stiffness Testing
- Compliance Testing
- Balloon Burst Testing
- Balloon Insertion Force Testing
- Balloon Retrieval Force Testing
- Balloon Friction Testing
- Balloon Deflation Testing
- Balloon Endoscope Compatibility Testing

Substantial Equivalence

The proposed Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter has the same design, and scientific technology as the Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter; and the same intended use population as the Predicate Boston Scientific CRE Dilatation Balloon (K112994). Both devices are of similar design and there were no new issues of safety or effectiveness with the proposed device. Please see the following Substantial Equivalence Comparison Table:

Substantial Equivalence Comparison Table

Design Feature	**Proposed** Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter – Wire Guided		**Predicate** Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter – Wire Guided (K143609)		**Predicate** Boston Scientific CRE™ Dilatation Balloon (K112994)		Comments
Indication for Use	The EZDilate 3-Stage Balloon Dilatation Catheters are indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.		The EZDilate 3-Stage Balloon Dilatation Catheters are indicated for use in adult populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.		The CRE™ Wireguided Balloon Dilatation Catheter is indicated for use in adult and adolescent populations to endoscopically dilate strictures of the alimentary tract. It is also indicated in adults for endoscopic dilatation of the Sphincter of Oddi with or without prior sphincterotomy.		Identical to the predicate Boston Scientific CRE™ Dilatation Balloon (K112994)
Balloon Length	5.5cm, 6.5cm		5.5cm, 6.5cm		5.5cm		Similar (The 6-7-8 and 8.5-9.5-10.5 balloons are 6.5cm)
Inflated Outer Diameter (OD)/Inflation Pressure (ATM)	**Inflated OD** 6-7-8 8.5-9.5-10.5 11-12-13 13.5-14.5-15.5 16-17-18 18-19-20	**Pressure ATM** 2.0-5.5-9.5 2.0-5.5-9.5 2.0-3.5-5.5 2.5-4.0-6.0 2.5-4.0-5.5 2.5-3.5-5.0	**Inflated OD** 6-7-8 8.5-9.5-10.5 11-12-13 13.5-14.5-15.5 16-17-18 18-19-20	**Pressure ATM** 2.0-5.5-9.5 2.0-5.5-9.5 2.0-3.5-5.5 2.5-4.0-6.0 2.5-4.0-5.5 2.5-3.5-5.0	**Inflated OD** 6-7-8 8-9-10 10-11-12 12-13.5-15 15-16.5-18 18-19-20	**Pressure ATM** 3-6-10 3.5-5-9 3-5-8 3-4.5-8 3-4.5-7 3-4.5-6	Similar (Identical maximum/minimum inflated outer diameters. Intermediate sizes may vary.)
Device Working Length	240 cm		240 cm		240 cm (Esophageal, Pyloric, Colonic & Biliary) 180 cm (Esophageal, Pyloric & Biliary)		Similar (Boston Scientific offers an additional length.)
Compatible Guidewire	0.035”		0.035”		0.035”		Identical
Semi-Compliant Balloon	Yes		Yes		Yes		Identical
Radiopaque Marker	Yes		Yes		Yes		Similar (Marker location may vary.)
Rounded balloon taper	Yes		Yes		Yes		Similar (Facilitates endoscopic visualization of the stricture through the balloon.)

Conclusion:

In summary, the Gyrus ACMI EZDilate 3-Stage Balloon Dilatation Catheter is substantially equivalent to the predicate devices and presents no new questions of safety or effectiveness.