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

June 22, 2017

Girgis Scope LLC
% E. Smith
Consultant
Smith Associates
1468 Harwell Avenue
Crofton, Maryland 21114

Re: K163412
Trade/Device Name: Girgis Scope Video 200 Double Bladed Laryngoscope (GSV200.DBL)
Regulation Number: 21 CFR 868.5540
Regulation Name: Rigid Laryngoscope
Regulatory Class: Class I
Product Code: CCW
Dated: May 23, 2017
Received: May 26, 2017

Dear E. Smith:

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,

Mark S. Fellman -S

for

Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental 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)*
K163412

Device Name
Girgis Scope Video 200 Double Bladed Laryngoscope (GSV200.DBL)

Indications for Use *(Describe)*
The Girgis Scope Video 200 Double Bladed Laryngoscope (GSV200.DBL) is indicated to improve direct visualization of larynx and assist in both non-complicated and difficult intubation in situation of unpredictable airway condition.

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

Sponsor

Company Name:	Girgis Scope LLC
Company Address:	2 Stonegate Drive Monroe Township, NJ 08831
Telephone:	1-732-710-9724
Fax:	1-732-605-1631
Contact Person:	Madgy Girgis, M.D.

Summary Preparation Date:	June 22, 2017
Trade Name:	Girgis Scope Video 200 Doubled Bladed Laryngoscope (GSV200.DBL)
Common/Usual Name:	Video Laryngoscope
Classification Name:	Laryngoscope Rigid Accessory
Regulation Code:	21 CFR 868.5540
Product Code:	CCW
Device Class:	Class I
Panel:	Division of Anesthesiology

Predicate Device

Manufacturer	Brand Name	Classification
Propper Manufacturing Company, Inc.	Propper Flip-Tip™ Laryngoscope	K915804

Device Description

GSV200.DBL is designed to assist in tracheal intubation procedure by direct visualization of laryngeal anatomy in closed position and use movable blade with camera as accessory from different angle in open position. The physical shape of GSV200.DBL is a modification of traditional Macintosh blade similar to Propper flip tip laryngoscope with added movable blade with camera as accessory to provide visualization to insert endotracheal tube.

Girgis Scope Video DBL is designed to use two power sources, one in the stationary handle

for fiber optic illumination of the airway and the second in the DVR monitor to illuminate the Larynx for the video camera. Battery chargers, cables to computer and cable to connect to TV screen are accessories included in the kit. The GSV200.DBL is provided non-sterile and is reusable and can be disassembled to provide cleaning and disinfection.

Indications for Use Statement

The Girgis Scope Video 200 Double Bladed Laryngoscope (GSV200.DBL) is indicated to improve direct visualization of larynx and assist in both non-complicated and difficult intubation in situation of unpredictable airway condition.

Predicate Product Comparison Table

Parameters	Girgis Scope LLC (K163412)	Propper Manufacturing Company, Inc. (K915804)	Comments
Indications for Use	The Girgis Scope Video 200 Double Bladed Laryngoscope (GSV200.DBL) is indicated to improve direct visualization of larynx and assist in both non-complicated and difficult intubation in situation of unpredictable airway condition.	Propper Flip Tip™ laryngoscope is indicated to improve direct visualization of larynx and assist in both non-complicated and difficult intubation in situation of unpredictable airway condition.	Identical
Type of Device	GVS200.DBL is a modification of the traditional MacIntosh laryngoscope. In addition to proper design movable blade and ratchet spring holder are attached.	Propper Flip-Tip™ Laryngoscope is a modification of the traditional MacIntosh laryngoscope.	Similar – Propper offers a flip tip at the distal end of the laryngoscope blade and the GSV200.DBL offers a second blade.
Design	Anatomically designed to improve visibility of the vocal cords and reduce teeth damage	Anatomically designed to improve visibility of the vocal cords and reduce teeth damage	Identical
Laryngoscope Flexi-Tip and Lever Control	Flexi-tip is adjustable to 70 degrees using levering movable handle to provide a precise control to expose the epiglottis.	Flexi-tip is adjustable to 70 degrees using levering movable handle to provide a precise control to expose the epiglottis.	Identical

Fiber Optic Intubating Laryngoscope	Stationary handle for fiber optic illumination of the mouth	Stationary handle for fiber optic illumination of the mouth	Identical
Power Supply and Light Source	Stationary laryngoscope handle containing a Lithium Ion rechargeable battery (3.7V). GSV200.DBL utilizes a rechargeable battery to power light bulb and through their 5mm fibro-optic bundle to provide bright white illumination.	Stationary laryngoscope handle containing battery. Propper utilizes AA and C Batteries to power light bulb and through their 5mm fibro-optic bundle to provide bright while illumination.	Predicate uses C batteries and the GSV200.DBL utilizes a rechargeable battery
Sterilization	Pre-vacuum sterilizer 132 degrees for 4 minutes	Pre-vacuum sterilizer 132 degrees for 4 minutes	Identical
Laryngoscope Blades	Reusable	Reusable	Identical

Discussion of Technological Characteristics

1. Propper Flip-Tip™ Laryngoscope blade (K915804) and the GBV200.DBL Laryngoscope both have a flexible tip that is adjustable to 70 degrees using a levering system which includes a movable handle, tip and spring mechanism and both offer fiber optic illumination.
2. Both devices are anatomically designed to improve visibility of the epiglottis and reduce teeth damage. Both devices provide a laryngoscope stationary handle containing batteries, Propper utilizes C Batteries and GBV200.DBL a rechargeable battery, to power light bulb through their fibro-optic bundle which provides bright white illumination.
4. Both systems have a stationary handle and in addition to the Propper design the GSV200.DBL uses a ratchet spring holder with a ball joint socket that locks the movable blade in closed position while introducing the two blades in patient mouth and unlocks to open position in step by step progression.
5. In addition to the Propper laryngoscope design, GSV200.DBL uses the movable blade, which is attached to the movable handle and articulates with stationary blade so movement in the movable handle is transmitted to the movable blade to:
    A. To create a pathway to introduce the endotracheal tube with ease
    B. The movable blade carries camera arrangement as accessory for indirect visualization of laryngeal anatomy in unpredictable difficult intubation. The camera angle will be looking upward and forward to show the most anterior position of larynx in difficult intubation
5. Both offer a reusable Flexi-Tip style laryngoscope blade, both recommend pre-vacuum sterilization at 132°C for 4 minutes.

Non-Clinical Performance Data

- IEC 60335-1 Corrigendum 1 – Household and similar electrical appliances – Safety – Part 1: General Requirements
- IEC 60335-2-29 Safety of household and similar electrical appliances – Safety – Part 2-29 Particular requirements for battery charges
- IEC 60950-1 Information technology equipment – Safety – Part 1: General requirements
- IEC 60601-1 + CORR 1 (2006) + CORR 2 (2007) + A1 (2012) Medical electrical equipment Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2:2007 Medical electrical equipment Part 1-2: Collateral standard: Electromagnetic compatibility – Requirements and tests
- USP 24, NF 19 Biological Test for Plastics, Class VI 70 degrees C
- AAMI/ANSI ST79 Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities
- ISO 10933-5 Biological Evaluation of Medical Devices – Part 5: Tests for in vitro Cytotoxicity L929 MEM Elution Test
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Test for Irritation and Skin Sensitization Kligman Maximization Test
- ISO 10993-10 Biological Evaluation of Medical Devices – Part 10: Test for Irritation and Skin Sensitization Intracutaneous Injection Test
- ISO 10993-11 Biological Evaluation of Medical Devices – Part 11: Tests for Systemic Toxicity
- ASTM F 756-08 Standard Practice for Assessment of Hemolytic Properties of Materials
- ASTN F 619-03 Standard Practice for Extraction of Medical Plastics
- A Simulated Use/Usability study was conducted using Anesthesiologists, Emergency Room Physicians, and Emergency Medical Service (EMS).
- Software Validation per *Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*

Clinical Study

No clinical studies were conducted.

Conclusion

The Girgis Scope Video 200 Double Bladed Laryngoscope model (GSV200.DBL) has the same indications for use, flexible tip design, fiber optic bundle for lighting, laryngoscope blade design, laryngoscope handle design, same methods of sterilization, and similar nonclinical testing and are battery operated as the Propper Flip-Tip Laryngoscope (K915804). The DVR accessory improves visualization of the epiglottis and the usability study demonstrated ease-of-use of the system. Based on the similarities of the two laryngoscope systems no different questions of safety and effectiveness have been raised and we conclude that our laryngoscope system is substantially equivalent to the predicate laryngoscope system.