

510(K) Summary

Sponsor

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Trade Name: Girgis Scope Video 200 Doubled Bladed Laryngoscope

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 high 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	Flexi-tip is adjustable to 70 degrees using levering movable handle to provide a	Identical

	precise control to expose the epiglottis.	precise control to expose the epiglottis.	
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
- ASTM 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 Proper 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.