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

November 10,2014

Yeescope Pty. LTD
c/o Paul Dryden, Consultant
Yeescope Pty. LTD
10 Binney Rd
Kings Park, New South Whales
2148

Re: K140951
Trade/Device Name: Yeescope Laryngoscope
Regulation Number: 21 CFR 868.5540
Regulation Name: Rigid Laryngoscope
Regulatory Class: I
Product Code: CCW
Dated: September 24, 2014
Received: September 25, 2014

Dear Mr. Dryden:

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" (21CFR 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,

Susan Runner DDS, MA

Erin I. Keith, M.S.
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)*
K140951

Device Name
Yeescope Laryngoscope

Indications for Use *(Describe)*
The Yeescope laryngoscope is a single use, disposable laryngoscope blade and handle that is intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

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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Yeescope Pty. Ltd.
10 Binney Road
KINGS PARK NSW 2148
AUSTRALIA

Official Contact: Kevin Yee – Managing Director
Tel: +61 2 9892 3400
Fax: +61 2 9892 3116

Proprietary or Trade Name: Yeescope Laryngoscope

Common/Usual Name: Rigid Laryngoscope

Classification Name: Rigid Laryngoscope
Product code – CCW
21 CFR 868.5540
Class 1

Predicate Devices: Truphatek Tru-MR™ - K062523

Device Description:
Yeescope laryngoscope blades and handles are single use, fully disposable laryngoscopes identical to our standard units except we have exchanged the battery to one that is less magnetic and thus would meet the requirements for MR conditional environments.

Yeescope laryngoscope are offered in one (1) style and two (2) sizes; Macintosh style (curved) and in Sizes 3 and 4.

Indications for Use:
The Yeescope laryngoscope is a single use, disposable laryngoscope blade and handle that is intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

Patient Population:
Patients who are to be intubated as determined by the clinician.

Environment of Use:
Adding Magnetic Resonance (MR) environments up to 3.0 Tesla strength.

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Comparison to Predicates

Features	Truphatek Tru-MR™ K062523	Proposed Device Yeescope MR
Indications for use	The Tru-MR ™ laryngoscope set is used to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.	The Yeescope laryngoscope is a single use, disposable laryngoscope blade and handle that is intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.
Environment of Use	MR environments Not to exceed 3.0 Tesla	Same Not to exceed 3.0 Tesla
Patient Population	Patients to be intubated	Patients to be intubated
Configurations	Handles Battery Blades	Handle Battery Blade (2 sizes) These are supplied assembled
Performance Testing	ASTM F2052-02 Standard Test Method of Magnetically Induced Displacement Force of Medical devices in the Magnetic Resonance Environment Pass criteria is deflection of < 45 degrees	ASTM F2052-02 Standard Test Method of Magnetically Induced Displacement Force of Medical devices in the Magnetic Resonance Environment Pass criteria is deflection of < 45 degrees Results degree deflection 23^{o} for Mac 4 and 25^{o} for Mac 3

Substantial Equivalence Discussion

The Yeescope laryngoscopes are viewed as substantially equivalent to the predicate device because:

Indications –

- Identical to predicate – K062523
- Intended to facilitate and aid in tracheal intubation in a Magnetic Resonance (MR) environment, not to exceed a 3.0 Tesla static magnetic field.

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Technology –

- Similar – handle, battery, blade design to predicate – K062523
- The Yeescope is an all plastic single use disposable while the predicate is metal and reusable
- Both devices are Class 1 exempt

Materials –

- The materials are part of a Class I exempt device.

Environment of Use –

- Identical to predicate – K062523
- Adding Magnetic Resonance (MR) environments up to 3.0 Tesla strength.

Patient Population –

- Identical to predicates – K062523
- Patients who are to be intubated

Performance Testing

- Identical to predicate K062523
- Testing has been performed according to ASTM F2052-02 for deflection in a 3.0 Tesla environment

Substantial Equivalence Conclusion -

The proposed device has been found to be substantially equivalent to the predicate. Differences between the proposed device and the predicate do not raise new questions of safety or efficacy.