January 12, 2018

A.R Guide In Medical Ltd.
% George Hattub
Senior Staff Consultant
MedicSense, USA
291 Hillside Avenue
Somerset, Massachusetts 02726

Re: K171411
Trade/Device Name: IRRIS (Infra-Red-Red Intubation System)
Regulation Number: 21 CFR 868.5730
Regulation Name: Tracheal Tube
Regulatory Class: Class II
Product Code: BTR
Dated: December 15, 2017
Received: December 20, 2017

Dear George Hattub:

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,

Tara A. Ryan -S

Digitally signed by Tara A. Ryan -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Tara A. Ryan -S, 0.9.2342.19200300.100.1.1=13000030749
Date: 2018.01.12 15:12:52 -05'00'

for
Tina Kiang, Ph.D.
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)*

K171411

Device Name

IRRIS (Infra-Red-Red Intubation System)

Indications for Use *(Describe)*

The IRRIS is intended for use as an aid in the placement of an endotracheal tube (ETT) during intubation procedures performed with video-assisted devices.

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

Pursuant to CFR 807.92, the following 510(k) Summary is provided:

1. (a) Submitter Address:

George J. Hattub
MedicSense, USA
291 Hillside Avenue
Somerset, MA 02726
george@medicsense.com

1. (b)	***Manufacturer Address:***	A. R Guide In Medical Ltd. 13 Wadi El Haj PO Box 1252 Nazareth, Israel 17111
	Mfg. Phone:	Tel.: +972-58-762-2811
	Contact Person:	Mr. Ariel Shrem, CEO
	Date:	December 28, 2017
2.	***Device & Classification Name:***	Tracheal Tube Accessory- classified as Class 2, BTR, Regulation Number 21 CFR 868.5730 IRRIS (Infra-Red-Red Intubation System)
3 a	***Predicate Device:***	K110962 Ambu aScope 2
3.	***Reference Devices:***	K954771- Laedal Medical Corporation- Trachlight Stylet and Tracheal LightWand K962361- Laedal Medical Corporation- Trachlight Stylet and Tracheal LightWand
4.	***Description:***	The IRRIS is designed for use as an aid in the placement of an endotracheal tube (ETT) during intubation procedures performed with video-assisted devices. The IRRIS is a non-invasive electronic illumination device. The device transmits light of a specific wavelength (near infra-red) to the underlying tissues. The light enables to illuminate the trachea of the patient, so it can be distinguished from other tissues while using video assisted devices (video-laryngoscopes).
5.	***Intended Use:***	The IRRIS is intended for use as an aid in the placement of an endotracheal tube (ETT) during intubation procedures performed with video-assisted devices.

6.	***Comparison of Technological Characteristics:***	With respect to intended use, IRRIS is the same as its predicate device. Although technology is somewhat different, the IRRIS is basically the same as its predicate device in that they produce light. The IRRIS is a non-invasive device, whereas the predicate device is invasive. Based upon the outcomes their extensive testing, evaluation, and analysis, A. R Guide In Medical believes that their device does not raise new concerns, and the IRRIS is substantially equivalent to its predicate devices. At the end of this summary, a comparison table is provided.
7.	***Performance Testing:***	**Non-Clinical Testing** The Biocompatibility of the device was confirmed by the following battery of tests: Cytotoxicity Study Using the ISO Elution Method ISO Skin Irritation Study in Rabbits ISO Closed Patch Sensitization Study in Guinea Pigs The outcome of this testing confirmed the biocompatibility of the patient contacting materials. Software Validation of the device was performed by a professional 3rd party service utilizing FDA's Guidance Document for Premarket Submission of Software Controlled Devices. The outcome of this testing confirmed its acceptability to predetermined requirements. As a medical electrical equipment, the device was tested in accordance with IEC 60601-1 by an independent lab. The outcome of this testing confirmed its compliance to the standard. The EMC of the device was confirmed by testing to IEC 60601-1-2 by an independent lab. The outcome of this testing confirmed its compliance to the standard.
		Clinical Testing: An IRB approved clinical trial was conducted on 12 patients outside of the USA. The results of the study verified the device aids in the placement of an ETT during intubation procedures performed with video-assisted devices by illuminating the trachea of the patient, so it can be distinguished from other tissues. There were no adverse reactions. Prior to conducting this study, 2 proof of concept studies were conducted on a total 6 cadavers to evaluate the clinical utility and usability of the IRRIS. The outcome of these studies confirmed the acceptability of the device to proceed on humans.

Feature and Characteristic	IRRIS (Subject Device)	Ambu aScope 2 (Predicate Device)
Description	The IRRIS is designed for use as an aid in the placement of an endotracheal tube (ETT) during intubation procedures performed with video-assisted devices. The IRRIS is a non-invasive electronic illumination device for single patient use. The device transmits light of a specific wavelength (near infra-red) to the underlying tissues. The light enables to illuminate the trachea of the patient, so it can be distinguished from other tissues while using video assisted devices (video-laryngoscopes).	Ambu aScope 2 is a flexible intubation scope System consist of a single use flexible intubation scope, Ambu, and a monitor. Ambu aScope 2 is for viewing anatomical structures in the upper airways, and as an aid in placement of an endotracheal tube (ETT), an ETT size 6 or larger can be used. A camera at the distal tip of the aScope provides the user with an indication of the placement of the aScope. The maneuverable tip allows the user to guide the ETT in the desired direction. Ambu aScope is for single patient use and it is sterile. The Ambu aScope 2 must be connected to Ambu aScope Monitor. The monitor displays the image and it is reusable.
Technical Description	An external disposable electronic illumination device for single patient use. The device is comprised of disposable LED lights (facing the patient skin) and is operated by a battery.	Ambu aScope System consist of a single use flexible intubation scope and a monitor. The scope comprised of flexible insertion cord with a maneuverable tip, CMOS camera and a LED light source at the distal tip of the scope. The scope has a handle with a control button giving the operator the ability to steer the tip of the scope up and down. The image is provided on a separate monitor.
Indications for Use	The IRRIS is intended for use as an aid in the placement of an endotracheal tube (ETT) during intubation procedures performed with video-assisted devices.	The Ambu aScope 2 is intended for use as an aid in the placement of an Endotracheal Tube (ETT) directly or through an intubating laryngeal mask during non-difficult and difficult intubating procedures or for a tracheostomy tube during percutaneous tracheostomy procedures. The Ambu aScope 2 achieves its purpose by providing the user with a visual confirmation of where the tip of the Ambu aScope 2 is in the human anatomy. The flexible tip of the Ambu aScope 2 allows the user to guide the ETT in the desired direction.
Intended Use	Same	Same

Intended User / Clinical Environment	Physicians or trained medical personnel having adequate familiarity with tracheal intubation and airway management in hospitals and pre-hospital settings	Physicians or trained medical personnel having adequate familiarity with tracheal intubation and airway management in hospitals settings
Site of application To Patient	Non-invasive patient's neck	Invasive via oropharynx, nasopharynx
Ancillary Equipment	Requires video-laryngoscopes	Require a separate monitor
Power Source	Battery	The monitor requires a battery
Technology	LED	LED and CMOS camera
Wave Length	~850 nm	Visible
Temperature	25 degrees C at surface	Unknown
Duration of use	10 minutes (sufficient for procedure)	The Ambu® aScope™ 2 can be used/switched on for a total of 8 hours from first plugged into the aScope Monitor.
Regulatory	Product Code BTR 21 CFR 868.5730	Product Code BTR 21 CFR 868.5730

Summary

Based on the results of the non-clinical performance testing, which included Biocompatibility Confirmation, Electrical Safety & EMC Tests, and Software Validation, as well as the outcomes from the pre-clinical cadaver studies and the performance in the clinical study, we believe that the IRRIS raises no new safety concerns or efficacy issues. Therefore, A.R. Guide In Medical believes that the IRRIS is substantially equivalent to it predicate device for its intended use.