July 11, 2019

Integrated Endoscopy, Inc.
Dr. Albert Rego
VP Regulatory & Quality
16 Technology Drive, Suite 165
Irvine, California 92618

Re: K191594
Trade/Device Name: Nuvis Battery Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: June 15, 2019
Received: June 17, 2019

Dear Dr. Rego:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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)*
K191594

Device Name
Nuvis® Battery Arthroscope

Indications for Use *(Describe)*

Integrated Endoscopy's Nuvis® Battery Arthroscope is an endoscopic device introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Integrated Endoscopy's Nuvis® Battery Arthroscopes are indicated for use in arthroscopic procedures performed in the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

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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K191594
510(k) Summary

I. **SUBMITTER:**

Integrated Endoscopy
16 Technology Dr. Ste. 165
Irvine, CA

Contact Person: Albert Rego, Ph.D.
Vice President Regulatory & Quality
Phone: 949.632.8126
Email: albert@iescope.com

Date Prepared: July 5, 2019

II. DEVICE:

Trade Name	*Nuvis®* Battery Arthroscope
Common/Classification Name:	Arthroscope, Class II
Regulation Number/Name:	21 CFR §888.1100, Arthroscope (Performance Standards)
Review Panel: Product Code:	Orthopedic/HRX, Arthroscope

III. PREDICATE DEVICE:

510(k) Number: K140903
Product Name: Nuvis® Arthroscope
Manufacturer: Integrated Endoscopy

IV. DEVICE DESCRIPTION:

Integrated Endoscopy's Battery Arthroscope is an optical instrument designed for illumination and visualization of internal anatomy of a patient within the knee, shoulder, and hip joint. Integrated Endoscopy's Battery Arthroscope has a 141mm working length, an outside diameter of 4mm, a field of view of 105°, and a direction of view of 30°. The Arthroscope is Battery Powered and three selectable light settings. The Arthroscope is designed to be used with a cannula compatible with a 4mm x 30° arthroscope with a working length of 141mm. The Arthroscope is supplied sterile and is for SINGLE USE ONLY. DO NOT REUSE OR RE-STERILIZE.

V. INDICATIONS FOR USE:

Integrated Endoscopy's *Nuvis® Battery Arthroscope* is an endoscopic device introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Integrated Endoscopy's *NuVis®* Battery Arthroscopes are indicated for use in arthroscopic procedures performed in the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).

VI. INTENDED USE:

The *Nuvis®* Battery Arthroscope is intended to be used as an endoscope in arthroscopic procedures performed on the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release) to view the surgical site.

VII. TECHNOLOGY CHARACTERISTICS:

The fundamental scientific technology of the previously cleared predicate device, Integrated Endoscopy *NuVis®* Arthroscope (K140903) is the same. The *Nuvis®* Battery Arthroscope utilizes an LED mounted on the inside the long tube of the scope to illuminate the surgical site, which is powered by a non-reusable battery placed within the surgical field.

VIII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The comparison of features and operation principles between *Nuvis®* Battery Arthroscope and *NuVis®* Arthroscope from Integrated Endoscopy is listed to below:

Table 13A. Comparison of *Nuvis®* Battery Arthroscope to Legally Marketed Predicate Devices

FEATURES AND SPECIFICATIONS	NUVIS® BATTERY ARTHROSCOPE (SUBJECT DEVICE)	NuVis™ ARTHROSCOPE (PREDICATE DEVICE)	SUBSTANTIALLY EQUIVALENT (YES/NO)
510(k) #	K191594	K140903	
General Information			
Name of Device	Nuvis Battery Arthroscope	Nuvis Arthroscope	YES
Manufacturer	Integrated Endoscopy	Integrated Endoscopy	YES
Device Description	Integrated Endoscopy's Battery Arthroscope is an optical instrument designed for illumination and visualization of internal anatomy of a patient within the knee, shoulder, and hip joint. Integrated Endoscopy's Battery	Integrated Endoscopy's NuVis® Arthroscope is a non-deflectable rigid endoscopic optical instrument designed for illumination and visualization of internal anatomy of a patient within the knee, shoulder, and hip joint. Integrated	YES

K191594
510(k) Summary

FEATURES AND SPECIFICATIONS	NUVIS® BATTERY ARTHROSCOPE (SUBJECT DEVICE)	NuVis™ ARTHROSCOPE (PREDICATE DEVICE)	SUBSTANTIALLY EQUIVALENT (YES/NO)
	Arthroscope has a 141mm working length, an outside diameter of 4mm, a field of view of 105 °, and a direction of view of 30 °. The Arthroscope is Battery Powered and three selectable light settings. The Arthroscope is designed to be used with a cannula compatible with a 4mm x 30° arthroscope with a working length of 141mm. The Arthroscope is supplied sterile and is for SINGLE USE ONLY. DO NOT REUSE OR RE-STERILIZE.	Endloscopy's **NuVis®** Arthroscope has a 140nm working length, an outside diameter of 4mm, a field of view of **105°,** and a direction of view of **30°.** The Arthroscope is designed to be used with a cannula compatible with a 4mm x **30°** arthroscope with a working length of 140mm. The Arthroscope is supplied sterile and is for Single Use Only. It is not intended to he re-used or re-sterilized.	
Indications for Use	Integrated Endoscopy's Battery Arthroscope is an endoscopic device introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Integrated Endoscopy's Battery Arthroscope is indicated for use in arthroscopic procedures performed in the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).	Integrated Endoscopy's *NuVis®* Arthroscope is an endoscopic device introduced into a patient to provide an internal view or image of the interior of a joint for examination, diagnosis, and/or therapy. Integrated Endoscopy's *NuVis®* Arthroscopes are indicated for use in arthroscopic procedures performed in the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release).	YES (Identical except for name)
Intended Use	The Nuvis Battery Arthroscope is intended to be used as an endoscope in arthroscopic procedures performed on the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release) to view the surgical site.	The Nuvis Arthroscope is intended to be used as an endoscope in arthroscopic procedures performed on the knee, shoulder, hip, wrist (carpel tunnel syndrome), temporal mandibular joint, ankle, elbow, and feet (plantar fascia release) to view the surgical site.	YES (Identical except for name)
Working Channel Length	141mm	140mm	YES
Diameter of Working Channel	4mm	4mm	YES

K191594
510(k) Summary

FEATURES AND SPECIFICATIONS	NUVIS® BATTERY ARTHROSCOPE (SUBJECT DEVICE)	NuVis™ ARTHROSCOPE (PREDICATE DEVICE)	SUBSTANTIALLY EQUIVALENT (YES/NO)
Field of View (FOV)	105°	105°	YES
Direction/Angle of View (AOV)	30°	30°	YES
Principle of Operation	The Nuvis Battery Arthroscope is essentially a long tube containing a series of optical and electrical components. At the distal end, the primary lens (lens 1) captures the image of the object at a 30° angle and with the aid of two mirrors transfers the image though a series of lenses inside the long tube to the clinician's eye piece at the proximal end. The image can be viewed at the Eye Piece or by a Camera Monitor System attached to the Eye Piece.	The operation principle of the *NuVis*® Arthroscope is similar to arthroscopes currently on the market used for the same indications for use and intended use. The major difference is in how the surgical site is illuminated. The *NuVis*® Arthroscope utilizes an in built LED that provides light to illuminate the surgical site being viewed. Most Arthroscopes on the market today incorporate a fiber bundle that carries the light from an external light source connected to it, to the surgical site. The LED of the *NuVis*® Arthroscope is energized by a custom power supply located outside the surgical field as described earlier in this section. The LED is connected to the power supply by means of 10 feet power cable.	YES
Method of Operation	The long tube of the endoscope is inserted into the body through a surgical incision and the tip of the scope is placed above the site that the clinician wants to visualize. The surgical site is illuminated by an LED inside the long tube at the distal end.	The *NuVis*® Arthroscope is essentially a long tube containing a series of optical and electrical components. At the distal end, the primary lens (lens 1) captures the image of the object at a 30 ° angle and with the aid of two mirrors transfers the image though a series of lenses inside the long tube to the clinician's eye piece at the proximal end. The image can be viewed at the Eye Piece	YES

K191594
510(k) Summary

FEATURES AND SPECIFICATIONS	NUVIS® BATTERY ARTHROSCOPE (SUBJECT DEVICE)	NuVis™ ARTHROSCOPE (PREDICATE DEVICE)	SUBSTANTIALLY EQUIVALENT (YES/NO)
		or by a Camera Monitor System attached to the Eye Piece.	
Sterilization	Supplied Sterile, EO sterilization	Supplied Sterile, EO sterilization	YES
Reusable	No, Single Use	No, Single Use	YES
General Specifications			
Resolution (Naked Eye)	1 to 5 times actual size depending on distance of distal tip from site being visualized.	1 to 5 times actual size depending on distance of distal tip from site being visualized.	YES
Resolution (Camera Monitor System)	Dependent on capability of the Camera Monitor System	Dependent on capability of the Camera Monitor System	YES
Materials of Construction	Stainless Steel, Copper, Glass, Sapphire, Medical grade plastics, adhesives	Stainless Steel, Copper, Glass, Sapphire, Medical grade plastics, adhesives	YES
Biocompatibility of Materials	Meets ISO 10993-1 requirements	Meets ISO 10993-1 requirements	YES
Electrical			
Light Source	LED	LED	YES
Power Supply	AA Alkaline Battery operates at <1W at approximately 3VDC	Input: 100-240VAC, 50-60Hz Output: variable output power of < 1W at approximately 3VDC	YES (Identical DC feed at LED)
Environment			
Operating Temperature	10°C to 40°C	10°C to 40°C	YES
Storage Temperature	10°C to 50°C	10°C to 70°C	YES
Relative Humidity	15% to 90%, Non-condensing	10% to 90%, Non-condensing	YES
Output Interfaces			
Cannula	Stryker	Stryker	YES
Camera Monitor System	Standard c-mount interface used for Endoscopes	Standard c-mount interface used for Endoscopes	YES
Output Interfaces			
Cannula	Stryker	Stryker	YES
Camera Monitor System	Standard c-mount interface used for Endoscopes	Standard c-mount interface used for Endoscopes	YES
Compliance			
Optics	Meets following standards requirements • ISO 8600-1 Third edition 2013- 03-01 • ISO 8600-3 First edition 1997- 07-01 • ISO 8600-5 First edition 2005- 03-15	Meets following standards requirements • ISO 8600-1 Third edition 2013- 03-01 • ISO 8600-3 First edition 1997- 07-01 ISO 8600-5 First edition 2005- 03-15	YES
Output Interfaces			
Cannula	Stryker	Stryker	YES

K191594
510(k) Summary

FEATURES AND SPECIFICATIONS	NUVIS® BATTERY ARTHROSCOPE (SUBJECT DEVICE)	NuVis™ ARTHROSCOPE (PREDICATE DEVICE)	SUBSTANTIALLY EQUIVALENT (YES/NO)
Camera Monitor System	Standard C-mount interface used for Endoscopes	Standard C-mount interface used for Endoscopes	YES
Compliance			
Optics	Meets following standards requirements • ISO 8600-1 Third edition 2013- 03-01 • ISO 8600-3 First edition 1997- 07-01 • ISO 8600-5 First edition 2005- 03-15	Meets following standards requirements • ISO 8600-1 Third edition 2013-03-01 • ISO 8600-3 First edition 1997- 07-01 • ISO 8600-5 First edition 2005- 03-15	YES
EMC Compliance	Meets following standards requirements • IEC 60601-1:2005, Edition 3.0 • IEC 60601-2-18 Edition 3.0 IEC 62471 First Edition	Meets following standards requirements • IEC 60601-1:2005, Edition 3.0 • IEC 60601-2-18 Edition 3.0 IEC 62471 First Edition	YES
Electrical Safety	Meets following standards requirements • IEC 60601-1:2005, Edition 3.0 • IEC 60601-2-18 Edition 3.0 IEC 62471 First Edition	Meets following standards requirements • IEC 60601-1:2005, Edition 3.0 • IEC 60601-2-18 Edition 3.0 IEC 62471 First Edition	YES
Degree of Protection-Arthroscope	Type BF-Applied Part	Type BF-Applied Part	YES
Enclosure Degree of Protection – Power Supply	IPX3	IPX1	YES
Disposal of Medical Device	Compliant with WEEE, RoHS, REACH, and Latex Free. Arthroscope discarded after a single use per hospital procedure for medical waste disposal and in accordance to national and local regulations and laws.	Compliant with WEEE, RoHS, REACH, and Latex Free. Arthroscope discarded after a single use per hospital procedure for medical waste disposal and in accordance to national and local	YES

IX. PERFORMANCE DATA SUMMARY:

The *Nuvis® Battery Arthroscope* was subjected to and passed electromagnetic compatibility (EMC), electrical safety and biocompatibility testing requirements. The *Nuvis®* Battery arthroscope met all specified design and performance requirements. The performance testing included comparison of images taken by the Integrated Endoscopy *Nuvis®* Battery Arthroscope and its predicate, the Integrated Endoscopy *NuVis®* Arthroscope.

Testing was performed on post-sterile devices to ensure device functionality and suitability for its intended use. The test regimen consisted of the following: visual inspection, leak and condensation test, visual image check, pointer/direction test, distal tip smoothness, scope diameter/cannula interface test, angle of view (AOV) measurement, field of view (FOV) measurement, resolution test, and LED light intensity verification, and PX3 Liquid Penetration and Ingress tests, biocompatibility testing, packaging testing (pouch seal and transportation), sterilization valuation testing, and shelf life stability testing.

All requirements were met for the *Nuvis®* Battery Arthroscope. Performance bench testing demonstrated the *Nuvis®* Battery Arthroscope can perform as intended.

ANIMAL

Animal studies were not performed nor required.

CLINICAL STUDIES

Clinical studies were not performed nor required.

X. VOLUNTARY SAFETY AND INTERNATIONAL AGENCY STANDARDS:

The following voluntary and international agency standards and guidelines were reviewed and are followed in the development of the *Nuvis®* Battery Arthroscope to ensure its safety and suitability for its intended use:

- AAMI/ANSI/JSO I 0993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
- AAMI/ANSI ES60601-I :2005/(R) 2012 and A 1:2012, medical electrical equipment - Part 1: general requirements for basic safety and essential performance.
- AAMI *I* ANSI/IEC 60601-1-2:2007/(R) 2012, Medical Electrical Equipment- Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility -Requirements and tests.
- IEC 60601-2-18 Edition 3.0 2009-08, Medical Electrical Equipment - Part 2: Particular Requirements for the Safety of Endoscopic Equipment.
- IEC 62471 First Edition 2006-07, Photobiological Safety of Lamps and Lamp Systems.
- ISO 8600-l Third edition 2013-03-0 I, Endoscopes -- Medical endoscopes and

endotherapy devices -- Part 1: General requirements.

- ISO 8600-3 First edition I 997-07-01, Optics and optical instruments - Medical endoscopes and endoscopic accessories - Part 3: Determination of field of view and direction of view of endoscopes with optics.
- ISO 8600-5 First edition 2005-03-15, optics and photonics - medical endoscopes and endotherapy devices - part 5: Determination of optical resolution of rigid endoscopes with optics.
- AAMI/ANSI/ISO 11135-1:2007, Sterilization of health care products -- Ethylene oxide -- Part I: Requirements for development, validation and routine control of a sterilization process for medical devices.
- AAMI /ANSI/ ISO 10993-7:2008(R) 2012, Biological Evaluation of Medical Devices- Part 7: Ethylene Oxide Sterilization Residuals.

XI. CONCLUSION

The information in this 510(k) submission demonstrated the *Nuvis® Battery Arthroscope* is substantially equivalent to its predicate device.

The Nuvis® Battery Arthroscope and the *NuVis®* Arthroscope are both orthopedic medical devices that are used during arthroscopic surgical procedures. The indications for use are the same for both subject and predicate devices. The safety and performance of the *Nuvis®* Battery Arthroscope has been validated through bench testing. These studies and tests demonstrated the subject device is at least as safe and effective as the predicate device. The difference in power sources between the subject and predicate devices do not pose new concerns for safety or effectiveness.

Integrated Endoscopy, Inc. believes that the *Nuvis®* Battery Arthroscope has similar benefits and no more risk of harm to the patient when compared to the predicate device. The information provided demonstrates the subject device is substantially equivalent to the predicate device.