510(k) SUMMARY (K140903)

Applicant:	Integrated Endoscopy Inc. 23141 Arroyo Vista, Ste. 100 Rancho Santa Margarita, CA 92688
Company Contact:	Anil Bhalani RA Consultant Phone: 949-596-9001 Email: anilbhalani@yahoo.com
Date Summary Prepared:	July 16, 2014
Trade Name:	*nuvis*™ Arthroscope
Common/Classification Name:	Arthroscope, Class II
Regulation Number/Name:	21 CFR §888.1100, Arthroscope (Performance Standards)
Review Panel:	Orthopedic
Product Code:	HRX, Arthroscope
Substantially Equivalent Devices:	Stryker Arthroscope [510(k) # K093677] Stryker Endoscopy, San Jose, CA Disposable Arthroscope [510(k) # K933576] United States Surgical Norwalk, CT 06856

Device Description:
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 Endoscopy's *nuvis*™ Arthroscope has a 140mm 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 be re-used or re-sterilized.

The *nuvis*™ Arthroscope is a long tube containing a series of lenses. At the distal end, a lens captures the image of the object and transfers it via a series of lenses along the long tube to the eye piece or Camera Monitor System at the proximal end of the arthroscope. The *nuvis*™ Arthroscope is made of materials that are commonly used in medical devices such as stainless steel, copper, glass, sapphire and plastics. The operating site is magnified by approx. two to five times its actual size depending on the distance between the tip of the endoscope and the object being visualized.

When a Camera Monitor System is connected to the *nuvis*™ Arthroscope's eye piece, through a video coupler of the Camera Monitor System, the image is further magnified depending on the type of video coupler and Camera Monitor System.

Indications for Use:
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).

Contraindications: None

Intended Use:
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.

Technology Characteristics:
The Fundamental Scientific Technology of the previously cleared predicate devices, Stryker Arthroscope [510(k) # K093677] and Disposable Arthroscope [510(k) # K933576] are the same. The *nuvis*™ Arthroscope utilizes an LED mounted on the inside the long tube of the scope to illuminate the surgical site, which is powered by a reusable Power Supply placed outside the surgical field.

Performance Data Summary:
The *nuvis*™ Arthroscope was subjected to and passed electromagnetic compatibility (EMC), electrical safety and biocompatibility testing requirements. The *nuvis*™ Arthroscope met all specified design and performance requirements. The performance testing also included comparison of images taken by the *nuvis*™ Arthroscope and its predicate, the Stryker Arthroscope.

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*™ Arthroscope to ensure its safety and suitability for its intended use:

- AAMI/ANSI/ISO 10993-1:2009, Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process.
- AAMI/ANSI ES60601-1:2005/(R) 2012 and A1:2012, medical electrical equipment - Part 1: general requirements for basic safety and essential performance.
- AAMI / 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 8600-1 Third edition 2013-03-01, Endoscopes -- Medical endoscopes and endotherapy devices -- Part 1: General requirements.
- ISO 8600-3 First edition 1997-07-01, 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 1: 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.

Substantial Equivalence: The technological differences between the n*uvis*™ Arthroscope and The predicate devices: Stryker Arthroscope [510(k) # K093677] and Disposable Arthroscope [510(k) # K933576] do not raise new questions of safety or effectiveness.

Conclusion:
The information in this 510(k) submission demonstrates that the n*uvis*™ Arthroscopes are substantially equivalent to its predicate devices and are as safe, as effective, and perform as well as or better than the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 17, 2014

Integrated Endoscopy Incorportion
Mr. Anil Bhalani
RA Consultant
23141 Arroyo Vista, Street 100
Rancho Santa Margarita, California 92688

Re: K140903
Trade/Device Name: NuVis Arthroscope
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope and Accessories
Regulatory Class: Class II
Product Code: HRX
Dated: April 8, 2014
Received: April 10, 2014

Dear Mr. Bhalani:

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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K140903

Device Name

Integrated Endoscopy's NuVis ™ Arthroscope

Indications for Use *(Describe)*

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).

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Joshua C. Nipper -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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