

K101734

SEP 08 2010

510(k) Summary of Safety and Effectiveness as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which Substantial Equivalence is based

1. **Date Prepared:** June 15, 2010

2. **510(k) Owner's Name:**
 VisionScope Technologies, LLC
 2352 Main Street, Suite 303
 Concord, MA 01742, USA

3. **Contact Information:**
 Lim Cheung, Ph.D.
 General Manager & CTO
 Telephone: 1-978-776-9512
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4. **Device Name**
Trade Name: VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
- Endoscopes (Accessories in four lengths)
- Sterile Procedure Kits (Accessories in four lengths)

Common Name: Endoscopes and Accessories: Video Systems, Image Capture, Light Source, Endoscopes, Fiber Optic

Classification Name: Endoscopes And/Or Accessories (21 CFR §876.1500): Video System, Image Capture, Light source, Endoscope, Fiber Optic Arthroscope (21 CFR §888.1100)

5. **Predicate Devices:**

Primary:		
InnerVue Diagnostic Scope System	K072879	Arthrotek Inc. (Biomet)
Secondary:		
Smith & Nephew HD Camera System	K070266	Smith & Nephew Endoscopy
Smith & Nephew Arthroscope	K072675	Smith & Nephew Endoscopy
Stryker LED Light Source (L9000)	K082813	Stryker Endoscopy
EndoSheath	K990354	Vision Sciences Inc.
Smith & Nephew 660HD Image Management System	K060777	Smith & Nephew Endoscopy

6. Description of Device

The VisionScope High Definition Endoscopy Camera System is made up of the following components:

- Integrated Camera Control Unit containing the camera control electronics, light source and image capture electronics
- Camera Handpiece
- VisionScope line of four Endoscopes of identical design except for the lengths
- VisionScope Disposable Sterile Procedure Kits in four matched lengths as the endoscopes

7. Indications for Use

The VisionScope High Definition Endoscopy Camera System is indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of an interior cavity of the body through a natural or surgical opening. Examples of generic surgical use include imaging of articular cavities, body cavities, hollow organs and canals.

Additionally, when used in conjunction with an appropriately indicated and FDA 510(k)-cleared endoscope and light source, the VisionScope High Definition Endoscopy Camera Control Unit and Camera Handpiece are indicated for use in arthroscopic and endoscopic surgical procedures to provide illumination, visualization and capture of still and motion pictures of articular cavities, body cavities, hollow organs and canals.

8. Comparison of Technological Characteristics

The VisionScope System similarities to the predicate devices are:

- Has the same intended use and indications for use
- Utilizes the same operating principle
- Incorporates the same basic design
- Incorporates the same technological characteristics
- Tested to the same electrical and electromagnetic safety standards for medical electrical equipment
- Manufactured under a quality system

9. Summary Performance Data

VisionScope conducted the verification and validation testing with the VisionScope High Definition Endoscopy Camera System to demonstrate safety and effectiveness and substantial equivalence to the predicate devices listed above. All verification and validation data demonstrate that the device is safe and effective and performs as intended.

The VisionScope System conforms to the following voluntary standards:

- ANSI/AAMI/ISO 11135-1:2007
- ISO 10993-7:2008
- ISO 10993-5:2009

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- ISO-10993-10:2002
- ISO 10993-11:2006
- UL 60601-1:2003 R4.06
- IEC 60601-1:1988 + A1:1991 + A2:1995,
- EN 60601-1:1990 + A1 + A2 + A13
- CAN/CSA 22.2 No. 601.1
- IEC 60601-1-4 / EN60601-1-4:2000
- IEC 60601-1-6: 2004 (First Edition) for use in conjunction with IEC 60601-1:1988 + A1:1991 + A2:1995
- EN 60601-1-2:2007
- IEC 60601-2-18:1996 Second Edition + A1:2000



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

VisionScope Technologies, LLC
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Re: K101734

Trade/Device Name: VisionScope High Definition Endoscopy Camera System with:

- Camera Control Unit
- Camera Handpiece
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- Sterile Procedure Kits (Accessories in four lengths)

Regulation Number: 21 CFR 888.1100

Regulation Name: Arthroscope

Regulatory Class: Class II

Product Code: HRX, GCJ

Dated: June 15, 2010

Received: June 21, 2010

Dear Dr. Cheung:

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

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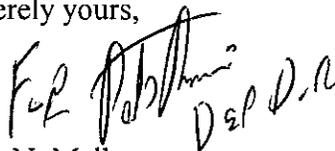
found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,

A handwritten signature in black ink, appearing to read 'Mark N. Melkerson', with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

K101734

510(k) Number (if known): K101734

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Device Name:

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Prescription Use Yes
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF
NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. P. Ogle
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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