



Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

June 2, 2016

Smith & Nephew
Ms. Janice Haselton
Principal Regulatory Affairs Specialist
150 Minuteman Road
Andover, Massachusetts 01810

Re: K153606

Trade/Device Name: Lens Camera Control Unit-WiFi, Lens Camera Unit-Non-WiFi, Lens
Camera Head, Camera Coupler, Tablet Application

Regulation Number: 21 CFR 876.1500

Regulation Name: Endoscope and accessories

Regulatory Class: Class II

Product Code: GCJ, HRX

Dated: May 3, 2016

Received: May 4, 2016

Dear Ms. Haselton:

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" (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.

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,

Jennifer R. Stevenson -A

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

Indications for Use

510(k) Number (if known)
K153606

Device Name

LENS Camera Control Unit-WiFi, LENS Camera Unit-Non-WiFi, LENS camera head, Camera Coupler and Tablet Application

Indications for Use (Describe)

The Lens Integrated system and LENS Camera Head are used in diagnostic and operative procedures for arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of surgical sites within articular cavities, body cavities, hollow organs and canals.

Additionally, the LENS Integrated System and Camera Head are indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.

The LENS Application, when used in conjunction with the LENS Integrated System WiFi version, is indicated for capture of still and motion pictures, patient file management and limited redundant control of the LENS camera control unit within articular cavities, body cavities, hollow organs, canals and the thoracic cavity.

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 OF SAFETY AND EFFECTIVENESS INFORMATION

as required by the Safe Medical Devices Act of 1990 and codified in 21 CFR 807.92 upon which the substantial equivalence is based.

Smith & Nephew LENS Integrated System and LENS Camera head

Date Prepared: December 15, 2015

A. Submitter's Name:

Smith & Nephew, Inc., Endoscopy Division
150 Minuteman Road, Andover, MA 01810

B. Company Contact

Janice Haselton
Principal Regulatory Affairs Specialist
Phone: (978) 749-1494

C. Device Name

Trade Name: LENS Camera Control Unit-WiFi, LENS Camera Unit-Non-WiFi,
LENS Camera Head, Camera Coupler and Tablet Application
Common Name: LENS Camera System
Classification Name: Endoscopes and Accessories per 876.1500.
Pro codes: GCJ, HRX

D. Predicate Devices

The Smith & Nephew LENS Integrated System and LENS camera head are substantially equivalent in intended use and fundamental scientific technology to the following legally marketed device in commercial distribution:

Primary: VisionScope High Definition Endoscopy Camera System, K101734

Secondary: 560 High Definition Camera System, K070266.

E. Description of Device

The Smith & Nephew LENS Integrated System is an integrated camera/ LED light source/ image management device that provides visualization, illumination and image capture combined in a single console. The LENS Integrated System control units will be offered in two versions, Wi-Fi and Non-Wi-Fi. The LENS Integrated system works in conjunction with the LENS camera head, appropriate light guides, couplers and endoscopes.

The optional LENS application acts as a tool to remotely capture still and motion pictures, patient file management and limited redundant control of the LENS control unit wirelessly from the LENS camera system.

The application provides the ability to view and annotate by voice or graphics or to text captured patient data and sharing of patient data via a USB storage device, email, or printing to the local tablet camera roll. The application is downloaded from the Apple APP store to a surgeon's tablet.

F. Intended Use

The LENS Integrated System and LENS camera head are intended to provide illumination, visualization and still and motion pictures of surgical sites. In addition the LENS Application is intended to capture still and motion pictures, and provide patient file management and limited redundant control of camera features.

Indications for Use

The Lens Integrated System and LENS Camera Head are indicated for use in diagnostic and operative arthroscopic and endoscopic procedures to provide illumination, visualization and capture of still and motion pictures of surgical sites within articular cavities, body cavities, hollow organs and canals.

Additionally, Lens Integrated System and LENS Camera Head are indicated for use in endoscopic surgical procedures in the thoracic cavity when used with an appropriately indicated thoracoscope.

The LENS Application, when used in conjunction with the LENS Integrated System Wi-Fi version, is indicated for capture of still and motion pictures, patient file management and limited redundant control of the LENS camera control unit within articular cavities, body cavities, hollow organs, canals and the thoracic cavity.

G. Comparison of Technological Characteristics

The Smith & Nephew LENS Integrated System and LENS camera head are substantially equivalent in design, materials, technological characteristics, intended use, and indications for use to the currently marketed predicate device, VisionScope High Definition Endoscopy Camera System K101734 in that:

- The proposed and predicate devices both have the same intended use and indications for use.
- Both the predicate and proposed devices have the same functional requirements.
- Video formats are similar.
- Both the proposed and predicate device use single chip technology.
- Both the proposed and predicate device utilize LED technology

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The similarities between the Smith & Nephew LENS Integrated System and Lens Camera Head and the 560 High Definition Camera Head are:

- Both the proposed and the predicate are constructed out of the same materials.
- Both the proposed and predicate device have the same FPGA based video processing.
- Both the proposed and predicate device have similar indications for use.
- Both the proposed and predicate device camera heads are CF rated for thoracic surgery.

The major differences between the proposed LENS Integrated System and LENS camera head to the predicate devices VisionScope High Definition Endoscopy Camera System are:

- The VisionScope High Definition Endoscopy Camera System offers sterile procedure kits. The LENS Integrated System does not offer sterile procedure kits.
- The Lens System is not for use in a doctor's office and the VisionScope High Definition Endoscopy Camera System can be used in the operating room and a doctor's office.
- The LENS system offers an optional APP feature that can be downloaded from the APP store to a surgeons tablet to remotely capture video recordings and image files from the LENS camera control unit. The VisionScope High Definition Endoscopy Camera System does not offer a tablet APP but communicates and transfers patient images and information only to a remote source over WIFI. Additionally the LENS provides redundant remote control for camera control unit function

The major differences between the proposed LENS Integrated System and LENS camera head to the secondary predicate devices 560 High Definition Camera system are:

- The 560 does not have image management or an LED light source incorporated into the control unit. The LENS Integrated System incorporates an LED light source, image management function and camera functionality within the control unit.
- The 560 High Definition Camera head utilizes 3 chip technology and the LENS camera head offers 1 chip technology.
- The 560 High Definition Camera System does not provide Wi-Fi functionality.
- The 560 High Definition Camera System does not offer an optional APP feature.

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H. Summary Performance Data

Software was developed, tested and verified per FDA guidance documents, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices” and IEC 62304: 2006 –Medical Device Software-Software Life Cycle Processes. The software for this device is considered a moderate level of concern.

Sterilization validation activities were performed in accordance with *AAMI TIR 12- Designing, testing, and labeling reusable medical devices for reprocessing in Health Care facilities: A guide for medical device manufactures.*

Bench testing was conducted to ensure that devices functioned as intended and met design specifications and acceptance criteria. Bench testing included light output testing, performance testing, thermal testing and ship testing.

In conclusion, based on the indications for use, technological characteristics, performance testing and comparison to the predicates, the Smith & Nephew LENS Integrated System raises no new questions of safety and effectiveness as compared to the predicate device Visionscope High Definition Endoscopy Camera System cleared in K101734 and the 560 High Definition Camera System, cleared in K070266 and are substantially equivalent to the predicate device in safety, effectiveness and performance.