March 23, 2022

Lazurite Holdings LLC
% Mike Goodson
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, 3rd Floor
Washington DC 20001

Re: K213860
Trade/Device Name: ArthroFree Wireless Surgical Camera System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and Accessories
Regulatory Class: Class II
Product Code: GCJ
Dated: December 9, 2021
Received: December 10, 2021

Dear Mike Goodson:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213860

Device Name
ArthroFree Wireless Surgical Camera System

Indications for Use *(Describe)*
The ArthroFree System is indicated for use in arthroscopy, general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery or wherever a laparoscope /endoscope/ arthroscope is indicated for use. The users of the camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons and urologists.

The ArthroFree System is indicated for use in diagnostic and operative endoscopic procedures, supplying illumination and visualization of an interior cavity of the body.

Examples of common general endoscopic surgeries are listed below.
• laparoscopic cholecystectomy
• laparoscopic hernia repair
• laparoscopic appendectomy
• laparoscopic pelvic lymph node dissection
• laparoscopically assisted hysterectomy
• laparoscopic and thorascopic anterior spinal fusion
• anterior cruciate ligament reconstruction
• knee arthroscopy
• shoulder arthroscopy
• small joint arthroscopy
• decompression fixation
• wedge resection
• lung biopsy
• pleural biopsy
• dorsal sympathectomy
• pleurodesis
• internal mammary artery dissection for coronary artery bypass
• coronary artery bypass grafting where endoscopic visualization is indicated
• examination of the evacuated cardiac chamber during performance of valve replacement

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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510(k) Summary

Device Trade Name: ArthroFree™ Wireless Surgical Camera System

Manufacturer: Lazurite Holdings LLC
5000 Euclid Avenue, Suite 206
Cleveland, OH 44103

Contact: Mike Goodson
Director, Regulatory Affairs
MCRA, LLC
202.552.5817

Prepared by: MCRA, LLC
803 7th Street NW, 3rd Floor
Washington, DC 20001
Office: 202.552.5800

Date Prepared: December 10, 2021

Classifications: Endoscope and accessories (21 CFR 876.1500)

Class: II

Product Codes: GCJ

Primary Predicate: Stryker Precision HD Camera System (K142603)

Indications For Use:
The ArthroFree System is indicated for use in arthroscopy, general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery or wherever a laparoscope /endoscope/ arthroscope is indicated for use. The users of the camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons, and urologists.

The ArthroFree System is indicated for use in diagnostic and operative endoscopic procedures, supplying illumination and visualization of an interior cavity of the body.

Examples of common general endoscopic surgeries are listed below.

- laparoscopic cholecystectomy
- laparoscopic hernia repair
- laparoscopic appendectomy
- laparoscopic pelvic lymph node dissection
- laparoscopically assisted hysterectomy
- laparoscopic and thoracoscopic anterior spinal fusion

- anterior cruciate ligament reconstruction
- knee arthroscopy
- shoulder arthroscopy
- small joint arthroscopy
- decompression fixation
- wedge resection
- lung biopsy
- pleural biopsy
- dorsal sympathectomy
- pleurodesis
- internal mammary artery dissection for coronary artery bypass
- coronary artery bypass grafting where endoscopic visualization is indicated
- examination of the evacuated cardiac chamber during performance of valve replacement

Device Description:
The ArthroFree System is a high-definition wireless camera system intended to transmit live video from a surgical site to a patient data console and surgical display during endoscopic surgical procedures. The ArthroFree System also enables the capture of still images and video from the live video stream by transmitting instructions for such capture to a patient data console when indicated by the user. The ArthroFree System is indicated for use in diagnostic and operative endoscopic procedures, supplying illumination and visualization of an interior cavity of the body.

Predicate Device:
Stryker Precision HD Camera System (K142603)

Performance Testing Summary:
The following testing was performed on the ArthroFree System.

- Sterilization and Cleaning Validations
- Software Verification and Validation
- Electrical Safety and Electromagnetic Compatibility
- Performance Verification and Validation
    - Light Engine Optical Output Validation
    - Extended High Level Functional Validation
    - Measured On-Screen Indicator Validation
    - Power Connector Validation
    - Video Signal and Battery Swap Time Validation
    - Wireless Latency Validation
    - Receiver Remote Trigger Validation
    - Firmware Functionality Validation
    - Battery Life Validation
    - Usability Validation

- Wireless Performance
    - FCC (Federal Communications Commission) Compliance
    - Wireless Co-Existence
- Human Factors and Usability Testing

Testing of the ArthroFree System indicated no new risks and demonstrated substantial equivalence in performance compared to the legally marketed predicate.

Substantial Equivalence:
The subject and predicate devices have the same indications for use and have similar technological characteristics. Both include reusable components intended to be sterilized before use by the end-user and components that are reusable and not intended to be re-sterilized. Comparative information and data presented in the 510(k) demonstrate substantial equivalence of the ArthroFree System to the Stryker Precision HD Camera System (K142603).

	Subject Device	**Predicate Device (K142603)**
Device Name	**ArthroFree Wireless Surgical Camera System**	**Stryker Precision HD Camera System**
Manufacturer	Lazurite	Stryker
Regulatory Information		
Classification	II	II
Regulation	21 CFR 876.1500	21 CFR 876.1500
Product Code	GCJ	GCJ
Clinical Characteristics		
Indications	The ArthroFree System is indicated for use in arthroscopy, general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery or wherever a laparoscope /endoscope/ arthroscope is indicated for use. The users of the camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons, neurosurgeons, and urologists. The ArthroFree System is indicated for use in diagnostic and operative endoscopic procedures, supplying illumination and visualization of an interior cavity of the body. Examples of common general endoscopic surgeries are listed below. • laparoscopic cholecystectomy • laparoscopic hernia repair	The Stryker Precision HD Camera System is indicated for use in general laparoscopy, nasopharyngoscopy, ear endoscopy, sinuscopy, and plastic surgery wherever a laparoscope/endoscope/arthroscope is indicated for use. A few examples of the more common endoscopic surgeries are listed below. • laparoscopic cholecystectomy • laparoscopic hernia repair • laparoscopic appendectomy • laparoscopic pelvic lymph node dissection • laparoscopically assisted hysterectomy • laparoscopic and thorascopic anterior spinal fusion

	Subject Device	Predicate Device (K142603)
Device Name	**ArthroFree Wireless Surgical Camera System**	**Stryker Precision HD Camera System**
	• laparoscopic appendectomy • laparoscopic pelvic lymph node dissection • laparoscopically assisted hysterectomy • laparoscopic and thoracoscopic anterior spinal fusion • anterior cruciate ligament reconstruction • knee arthroscopy • shoulder arthroscopy • small joint arthroscopy • decompression fixation • wedge resection • lung biopsy • pleural biopsy • dorsal sympathectomy • pleurodesis • internal mammary artery dissection for coronary artery bypass • coronary artery bypass grafting where endoscopic visualization is indicated • examination of the evacuated cardiac chamber during performance of valve replacement	• anterior cruciate ligament reconstruction • knee arthroscopy • shoulder arthroscopy • small joint arthroscopy • decompression fixation • wedge resection • lung biopsy • pleural biopsy • dorsal sympathectomy • pleurodesis • internal mammary artery dissection for coronary artery bypass • coronary artery bypass grafting where endoscopic visualization is indicated • examination of the evacuated cardiac chamber during performance of valve replacement The users of the camera are general surgeons, gynecologists, cardiac surgeons, thoracic surgeons, plastic surgeons, orthopedic surgeons, ENT surgeons and urologists.
Technical Characteristics		
System Components	Wireless Camera Head Battery & Battery Charger Receiver Sterilization Tray Cables	Camera Head and Coupler Camera Control Unit (CCU) Cables
Imaging System	High definition	Same as subject device
Compatible With Most Endoscopes Via C-Mount	Yes	Same as subject device
Principles of Operation	Light is projected to illuminate a body cavity. The image data is processed to provide a video stream sent to a display unit for viewing.	Same as subject device
Camera Head Control Buttons	Yes	Same as subject device
Software Level of Concern*	Moderate	Same as subject device

	Subject Device	Predicate Device (K142603)
Device Name	**ArthroFree Wireless Surgical Camera System**	**Stryker Precision HD Camera System**
Safety Standards	AIM 7351731 Rev. 2.00 IEC 60601-1 IEC 60601-1-2 IEC 60601-1-6 IEC 60601-2-18 IEC 60825-1 IEC 62133-2 IEC 62471	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-2-18 IEC 60825-1
Light Source	Built-in	Some models use a built-in light source, and some models use an external light source
Laser Safety Classification	Class 1	Same as subject device
Sterilization Characteristics		
Sterilization Status	Provided non-sterile to end-user	Same as subject device
Sterilization Method for Components Requiring Sterilization	Vaporized Hydrogen Peroxide (VHP)	Steam
Includes Components not Intended to be Sterilized	Yes	Same as subject device
Biological Characteristics		
Patient Contacting	Non-patient contacting	Same as subject device

*Per FDA guidance - *Content of Premarket Submissions for Software Contained in Medical Devices (2005)*