January 12, 2021

CIT Ortho, LLC
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services
1000 Westgate Drive, Suite #510k
Saint Paul, Minnesota 55114

Re: K203526/S001
Trade/Device Name: C Scope™ Visualization System
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 11, 2020
Received: January 8, 2021

Dear Prithul Bom:

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K203526

Device Name
C Scope Visualization System

Indications for Use *(Describe)*
The C Scope Visualization System is indicated to be used by a trained physician to provide illumination and visualization in arthroscopic procedures of an interior cavity of the body through a surgical opening.

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

Applicant:	CIT Ortho, LLC 26202 Detroit Rd. Ste. 340 Westlake, Ohio 44145
Company Contact:	Megan Lecavalier Chief Operating Officer Phone: 440-772-1421 Fax: 440-772-1422 Email: mlecavalier@clearimg.com
Date Summary Prepared:	December 28, 2020
Trade Name:	C Scope™ Visualization System
Common Name:	Arthroscope
Classification Name:	Arthroscope, Class II
Product Code:	HRX
Regulatory Class:	Class II
Regulation Number:	21 CFR §888.1100
Predicate Device:	NeedleCam HD Visualization System [K143705] BioVision Technologies, Golden, CO

Device Description:
The C Scope Visualization System is an arthroscope that allows users to illuminate and visualize patient anatomy during minimally-invasive arthroscopic procedures. The system consists of a single-use rigid Scope, a reusable Handpiece and a Tablet for viewing the images. The Scope contains a CMOS camera chip to visualize and an optical fiber to illuminate anatomical structures. The Scope includes an integral drape which covers the Handpiece to provide a sterile gripping surface for the user. The Scope is packaged in a sterile C Scope Disposable Scope Kit containing single use items syringe, tubing, cannula, and trocar to aid in the procedure. The Handpiece provides control of the direction and depth of the Scope and allows the user to capture images and videos. The reusable tablet Viewing Tablet is loaded with custom ImageClear software which provides image and video display and data management.

Indications for Use:
The C Scope Visualization System is indicated to be used by a trained physician to provide illumination and visualization in arthroscopic procedures of an interior cavity of the body through a surgical opening.

Intended Use:
The C Scope Visualization system is intended to visualize an interior cavity of the body.

Technology Characteristics:
The technological characteristics of the C Scope Visualization System are similar to its predicate device –

NeedleCam HD Visualization System (K143705). The indications and contraindications listed in this submission are in congruence between these devices. The C Scope Visualization system utilizes a disposable arthroscope, included in a sterile kit with supplemental instruments. The disposable scope connects to a reusable handpiece to display a live image on a viewing tablet with custom software for image processing and capture.

Comparison to Predicate Device:
The fundamental scientific technology of the C Scope Visualization System and the previously cleared predicate device, NeedleCam HD Visualization System [K143705], are the same. The table below shows relevant similarities and differences.

Table 1- Predicate Comparison

Feature	Subject Device C Scope Visualization System	Predicate Device NeedleCam HD Visualization System
FDA Classification	Class II	Class II
Product Code(s)	HRX	HRX/GCJ
Regulation Number	21 CFR §888.1100	21 CFR §888.1100/ 876.1500
Regulation Name	Arthroscope	Arthroscope/ Laparoscope, General & Plastic Surgery
Indications for Use / Intended Use	**Intended Use** The C Scope Visualization System is intended to visualize an interior cavity of the body.	**Intended Use** The Needle Cam HD™ Visualization System is intended to visualize an interior cavity of the body.
	Indications for use The C Scope Visualization System is indicated to be used by a trained physician to provide illumination and visualization in arthroscopic procedures of an interior cavity of the body through a surgical opening.	**Indications for Use** Needle Cam HD™ Visualization System is indicated to be used by a trained physician to provide illumination and visualization of an interior cavity of the body through a natural or surgical opening in diagnostic and operative arthroscopic and endoscopic procedures. Examples of surgical use include but are not limited to procedures on the knee, shoulder, ankle, elbow, wrist, shoulder, temporomandibular joint (TMJ), spinal, ophthalmic, ENT, and cervix.
Where Used	Hospital / Doctor's Office	Hospital / Doctor's office
Device Description	The C Scope Visualization System Includes the following components:	NeedleCam HD Visualization System includes the following components:
	• Tablet with custom software for image/video processing and display, capture and USB data	• An Image Capture Box with custom software for image/video processing display, capture, and USB

Feature	Subject Device C Scope Visualization System	Predicate Device NeedleCam HD Visualization System
	management, and external power supply	data management, and external power supply. • Video Outputs for external monitor
	• Reusable handpiece with LED light source.	• Reusable Camera-handpiece with an LED light source
	• Disposable single-use sterile kit including a semi-rigid scope with integral drape, and supplemental instruments including a cannula, trocar/obturator, and syringe and tubing for flushing.	• A disposable single-use sterile kit including a semi-rigid fiberoptic scope with integral drape, and supplemental instruments including a cannula, trocar, obturator, and cannula plug.
Single Use/Reusable	Tablet and Handpiece: Reusable. Scope and instruments: Sterile, Single Use.	Image capture box and camera handpiece: Reusable. Scopes & instruments: Sterile, Single Use
Sterilization	Scope kit – Ethylene Oxide (EO) sterilization	Scope kit – Ethylene Oxide (EO) sterilization
Sterility, How Supplied	Scope Kit – sterile in PETG tray w/ sealed LLDPE header pouch Tablet, Handpiece - non-sterile in cardboard packaging with protective padding	Scope Kit – sterile in PETG tray w/ sealed Tyvek lid. Camera Handpiece and Image Capture Box- non-sterile in cardboard packaging with protective padding
Image Acquisition	Image acquisition is achieved through the camera, which is a CMOS sensor located in the scope.	Image acquisition is achieved through the camera, which is a CCD sensor located in the handpiece.
Connectivity	The scope w/ camera connects to the handpiece with a quick release connector. The handpiece (with illumination source) and cable connects to the Tablet through USB connection.	The scope connects to the camera handpiece with a quick release connection. The handpiece (with illumination source) cable connects to the Image Capture Box through a custom electrical connection.
Image Display(s)	All-in-one Tablet	External display connection
Data Storage	Images and video automatically stored to Tablet. Images and video can be exported to USB device.	Image and video storage to USB device.
Type of Light Source	LED	LED
Camera Sensor	CMOS	CCD

Feature	Subject Device	Predicate Device
	C Scope Visualization System	NeedleCam HD Visualization System
Endoscope coupler	Built-in	Built-in
Materials	Commonly used medical-grade plastics and stainless steel	Commonly used medical-grade plastics and stainless steel

Based on the evaluation of the performance characteristics, construction, and indications of use, CIT Ortho has concluded that the C Scope Visualization System is substantially equivalent to the predicate device listed in this submission.

Performance Data Summary:
Determination of substantial equivalence is based on an assessment of non-clinical performance test data. The C Scope Visualization System has successfully completed the following relevant performance testing to demonstrate substantial equivalence. Testing was performed to evaluate physical integrity, functionality, and performance of the system.

The results of these tests provide reasonable assurance that the C Scope Visualization System has been designed and tested to assure conformance to the requirements for its intended use and indications for use. No new safety or performance issues were raised during the testing; therefore, this device is considered to be substantially equivalent to the predicate device.

Environmental and Packaging
The sterile packaging for the Disposable Scope Kit of the C Scope Visualization system was verified for transportation and environmental conditions according to ASTM D4169-16 DC-13 and ASTM D4332-14. Seal formation for the sterile LLDPE header pouch was validated per ISO 11607-2 2019 (E).

Mechanical and Durability
Testing was performed to verify the mechanical integrity and durability of the C Scope Visualization system. Testing also included ingress protection testing per IEC/EN 60529:2013 and luer testing per ISO 80369-7:2016. These tests demonstrated that the system met all product requirements.

Human Factors
Human factors validations were performed per Guidance for Industry and FDA Staff “Applying Human Factors and Usability Engineering to Medical Devices.” Two formative studies and one summative validation study were conducted utilizing the complete C Scope Visualization System in a production-equivalent state.

Electrical Safety and Electromagnetic Compatibility

Electrical safety and Electromagnetic Compatibility (EMC) testing were conducted on the C Scope Visualization System consisting of the Tablet, Handpiece, and Disposable Scope. The system complies with the IEC 60601-1:2012 and IEC 60601-2-18:2009 standards for safety with the Disposable Scope being a type BF applied part. The system complies with the IEC 60601-1-2:2014 standard for EMC. Immunity of the system to RFID readers was verified using AIM 7351731.

Software Validation and Verification Testing

Software verification and validation testing were conducted and documentation was provided as recommended by FDA’s Guidance for Industry and FDA Staff, “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices.” The software for this device was considered as a “moderate” level of concern, since a failure or latent flaw in the software could indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care

provider. Software validation was conducted according to AAMI/IEC 62304:2006/A1:2016 and FDA's Guidance for Industry and FDA Staff "General Principles of Software Validation."

Biocompatibility Testing

The patient-contacting components of the device are categorized as Externally Communicating Device, Tissue and Bone, Limited Contact (≤ 24 hours). Per ISO 10993-1:2018, the following testing was conducted:

- ISO 10993-5:2009 Biological evaluation of medical devices Part 5: Tests for in vitro cytotoxicity
- ISO 10993-10:2013 Biological evaluation of medical devices Part 10: Tests for irritation and skin sensitization
- ISO 10993-11:2018 Biological evaluation of medical devices Part 11: Tests for systemic toxicity
- ISO 10993-17:2009 Biological evaluation of medical devices Part 17: Establishment of allowable limits for leachable substances
- ISO 10993-18:2020 Biological evaluation of medical devices Part 18: Chemical characterization of medical device materials within a risk management process

Documentation for the biocompatibility testing was provided as recommended by Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.'"

Sterilization and Shelf Life

The C Scope Visualization System Disposable Scope Kit sterilization process, using 100% Ethylene Oxide (EO), has been validated in accordance with ISO 11135-1:2014 to achieve a SAL of 10^{-6}. EO and ECH residuals were below the limits specified in ISO 10993-7:2008 Amd 1:2019 (E). Both baseline and accelerated shelf-life testing were conducted demonstrating the device will perform as intended to support the proposed shelf-life. Accelerated aging testing was carried out according to ASTM F1980:2016.

Reprocessing of the reusable C Scope Handpiece was validated through a Manual Cleaning Validation, including Simulated Use, and an Intermediate Level Disinfection Validation. These studies were conducted in accordance with AAMI TIR12:2010, AAMI TIR30:2011 (R2016), and "Guidance for Industry and FDA Staff – Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling."

Animal Testing

No animal studies were required to demonstrate substantial equivalence.

Clinical Testing

No clinical studies were required to demonstrate substantial equivalence.

Conclusion

CIT Ortho concludes through a review of the benchtop assessments, the comparison of the device classification, intended use, operating principle, technological characteristics, sterility, and biocompatibility that the C Scope Visualization System is substantially equivalent to the predicate device and is as safe, as effective, and performs as well as or better than the predicate device.