February 25, 2025

Periwinkle Technologies Pvt. Ltd
% Ankur Naik
Managing Director
IZiel Healthcare
Pentagon P1, Office No. 601 and 604, Magarpatta City
Pune, Mab 411028
INDIA

Re: K233043
Trade/Device Name: Smart Scope® CX
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: Class II
Product Code: HEX

Dear Ankur Naik:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 14, 2024. Specifically, FDA is updating this SE letter to correct a typo in the device trade name.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jason R. Roberts, Ph.D., OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, (240) 402-6400, Jason.Roberts@fda.hhs.gov.

Sincerely,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

June 14, 2024

Periwinkle Technologies Pvt. Ltd
% Ankur Naik
Managing Director
IZiel Healthcare
Pentagon P1, Office No. 601 and 604, Magarpatta City
Pune, Mab 411028
INDIA

Re: K233043
Trade/Device Name: Smart Scope® (CX)
Regulation Number: 21 CFR 884.1630
Regulation Name: Colposcope
Regulatory Class: Class II
Product Code: HEX
Dated: May 9, 2024
Received: May 10, 2024

Dear Ankur Naik:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Reginald K. Avery -S

for Jason R. Roberts, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K233043

Device Name
Smart Scope® CX

Indications for Use *(Describe)*
Smart Scope® CX is intended for gynecological examination. It provides a portable means of magnified visualization of the tissues of the vagina, cervix, and external genitalia to aid in diagnosing abnormalities and selecting areas for biopsy. The Net4Medix® application is intended to provide documentation of the image in the field of view of the scope. The Smart Scope® CX camera probe is intended to be inserted into the vagina via a speculum by trained medical personnel in hospitals, clinics, and private offices, and is not intended for home use.

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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PRAStaff@fda.hhs.gov

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510(k) Summary

510(k) summary of substantial equivalence for Smart Scope® CX is provided in accordance with 21 CFR 807.92.

Date Prepared:	14 June 2024
Submitter (Owner):	Veena Moktali Founder & CEO Periwinkle Technologies Pvt Ltd. B1, Samrat Ashok CHS, S. No. 88/2, Veerbhadra Nagar, Baner, Pune - 411045, Maharashtra, India. P: +91 9021147173 Email: vrmoktali@periwinkletech.com
510(k) Contact Person:	Ankur Naik Managing Director IZiel Healthcare 14, Hadapsar Industrial Estate, Hadapsar, Pune – 411013, India. P: +91 72762 2555 M: +91 7069553814 Email: ankur.naik@izielhealthcare.com
Device Trade Name:	Smart Scope CX
Device Common Name	Colposcope
Classification Number:	21 CFR 884.1630
Classification Name:	Colposcope
Review Panel:	Obstetrics/Gynecology
Device Class:	Class II
Product Code:	HEX
Predicate Device:	Pocket Colposcope System (K181034) The predicate device has not been subjected to a design-related recall.

Device Description

Smart Scope® CX is a handheld, reusable transvaginal digital examination camera designed for use in a hospital or clinical setting. It is intended for close examination and magnified visualization of the external genitalia, vagina, and cervix. The Smart

Scope® CX was designed, developed, and manufactured at Periwinkle Technologies Pvt. Ltd. The model number is indicated below:

Model Number	Model Name	Model Description
CX	Smart Scope® CX	Digital Cervical Examination (Trans-vaginal)

The Smart Scope® CX packaging includes:

- Smart Scope® CX Probe
- Lenovo Smart Tab M8 Tablet with Net4Medix® Software
- Stand for tablet.
- Tablet charger.

The Smart Scope® CX camera probe is equipped with an integrated green and white LED light, which serves to illuminate the object under observation. Additionally, it features a 10X magnification camera, facilitating the capture of color images. Users can switch between the white and green light illumination and zoom in or out to capture images at different working distances by pressing respective buttons in the smart scope probe. By establishing a USB connection between the Smart Scope and a tablet, users can access live images and capture necessary stills using the Net4Medix® application, installed on the tablet. These captured images are then stored directly on the tablet. The Net4Medix® software further enables the creation and management of patient records, visit histories, and seamless integration with the Smart Scope® CX for functions such as image streaming, capture, storage, and assignment to the respective patient records.

The Smart Scope® CX is designed and intended to be used only with speculum and it is not intended to come into direct contact with the body. Smart Scope® CX is not a substitute for histopathology and is not a diagnostic test.

The Smart Scope® CX should be connected to the tablet via USB connections. The Smart Scope® camera probe is powered from the tablet through a connected USB interface. During the tablet's charging process, the device cannot be utilized. The Smart Scope® CX is intended to be used only with a Smart tablet that is customized and supplied with the device.

To enhance security and manageability, Periwinkle Technologies Pvt Ltd has pre-loaded the tablet with Enterprise-Device-Management (EDM) software. This software serves as a tool for the secure distribution of the Net4Medix® application and facilitates policy control for data security. This security framework restricts the usage of any software other than Net4Medix®, ensuring that the tablet is dedicated exclusively to this critical application. Consequently, users are unable to connect to external networks or access other internet facilities.

Specification:

Parameters	Specification
Operating System	Android 6+ operating system
Dimensions	211 x 124 x 8.2 mm or a similar
Display Screen	Touchscreen with 7 to 8-inch display Min. Resolution 1280X800, Gamut 60% NTSC, 84.6% sRGB, Brightness 350+ Nits, Contrast 552+
Battery capacity	4000+ mAh
Minimum storage capacity	16 GB
Minimum RAM.	2 GB

Smart Scope Features:

The Smart scope device is used like other colposcopes, and has the following features:

- Camera & Lens: 0° lens, 5 Mega Pixel CMOS sensor
- Light Source: Four (**4**) white and four (**4**) green LEDs arranged in a circular at the probe tip.
- Probe (Nozzle): 74 mm in length, 22.4 mm of Outer Diameter.
- Probe (Handle): 134.3 mm in length.
- Zoom, light controls on the probe handle.
- Image capture and pdf report generated through the Net4Medix® application.
- USB 2.0 cable attached to scope handle to connect to a tablet.
- Packaged non-sterile and designed for reuse after cleaning and Disinfection.
- High-definition output.

Intended Use / Indications for Use

Smart Scope® CX is intended for gynecological examination. It provides a portable means of magnified visualization of the tissues of the vagina, cervix, and external genitalia to aid in diagnosing abnormalities and selecting areas for biopsy. The Net4Medix® application is intended to provide documentation of the image in the field of view of the scope. The Smart Scope® CX camera probe is intended to be inserted into the vagina via a speculum by trained medical personnel in hospitals, clinics, and private offices, and is not intended for home use.

Substantial Equivalence Discussion

The **Pocket Colposcope (K181034)** has been selected as the primary predicate device for the substantial equivalence discussion regarding the Smart Scope® CX. The details regarding the substantial equivalence between the subject device and the predicate devices are explained below:

Comparison to predicate devices:

Table 1: Comparison to Predicate Device

Comparable Properties	Subject Device	Predicate Device (K181034)	Comparison Results
Product Name	Smart Scope® CX	Pocket Colposcope	Not Applicable
Manufacturer	Periwinkle Technologies Pvt Ltd	Hadleigh Health Technologies, LLC	Not Applicable
Regulation Number	21 CFR 884.1630	21 CFR 884.1630	Identical
Product Code	HEX	HEX	Identical
Product Class	Class II	Class II	Identical
Indication for Use	Smart Scope® CX is intended for gynecological examination. It provides a portable means of magnified visualization of the tissues of the vagina, cervix, and external genitalia to aid in diagnosing abnormalities and selecting areas for biopsy. The Net4Medix® application is intended to provide documentation of the image in the field of view of the scope. The Smart Scope® CX camera probe is intended to be inserted into the vagina via a speculum by trained medical personnel in hospitals, clinics, and private offices, and is not intended for home use.	The Pocket Colposcope is a digital video colposcope intended for gynecological examination. It provides a portable means of magnified visualization of the tissues of the vagina, cervix, and external genitalia in order to aid in diagnosing abnormalities and selecting areas for biopsy. The image system is intended to provide documentation of the image in the field of view of the colposcope. The Pocket Colposcope System is intended to be inserted into the vagina via a speculum by trained medical personnel in hospitals, clinics, and private offices, and is not intended for home use.	Similar
Multiple Use	Yes	Yes	Identical
Prescription (Rx only)	Yes	Yes	Identical

Comparable Properties	Subject Device	Predicate Device (K181034)	Comparison Results
Anatomical Site	External genitalia, vagina, and cervix	Cervix, vagina, and external genitalia	Identical
Intended User	Trained medical professionals	Trained medical professionals	Identical
Use Environment	Hospitals, clinics, and private offices	Hospitals, clinics, and private offices	Identical
Device Design		 	Not Applicable
Standard Configuration	Digital Camera connected to Tablet via USB cable and used without stand.	Digital CMOS camera used without stand.	Identical
External Power Source	Voltage: 5V Frequency: DC Input power: USB 5V from a tablet device	Voltage: 5V Frequency: DC Input power: USB 5V	Identical
Materials	Housing: Acrylonitrile-butadiene-styrene (ABS) Plastic Buttons: Thermoplastic polyurethane Camera protector: Glass	Housing: ABS Plastic Lens: PMMA	Different The housing of the subject and predicate device is made up of ABS plastic. The other subject device components are made of other plastics or glass that differ from the predicate device.

Comparable Properties	Subject Device	Predicate Device (K181034)	Comparison Results
			However, the differences do not raise different questions of safety and effectiveness.
Fundamental Scientific Technology	The camera has optics that relay optical information (live streaming of images) to a smart tablet (visualization/ annotation module).	The camera has optics that relay optical video information to a PC or laptop (visualization/ annotation module).	Different The Net4Medix application is installed on the Smart Tablet and aids in visualization and annotation. The predicate device required a PC or laptop to relay and visualize the optical information. This difference does not raise different questions of safety and effectiveness.
Device Specification: Light			
Light Module	LEDs in circular form.	Single loop group LED light	Identical
Light Source	White and green LED light	White and green LED light	Identical
Light Source Lifetime	≥ 10,000 hrs	≥ 10,000 hrs	Identical
Maximum Illumination	White-450 lux at working distance of 35-40mm Green-550 lux at working distance of 35-40mm	20,000 lux at a working distance of 5mm. 462 lux at a working distance of 50mm.	Different The illumination of the subject device does not exceed

Comparable Properties	Subject Device	Predicate Device (K181034)	Comparison Results
			the illumination for the predicate device. These differences do not raise different questions of safety and effectiveness.
Illumination Range/Beam Diameter	75 mm at a working distance of 40 mm	74.5 mm at working distance of 50 mm	Different The subject and predicate device have a similar illumination range at different working distances. These differences do not raise different questions of safety and effectiveness. .
Device Specification: Camera			
Magnification	29 or 46X on tablet display depending on orientation	3X-52X	Different The magnification of the subject device is within the range specified by predicate device. This does not raise any different questions of safety and effectiveness.

Comparable Properties	Subject Device	Predicate Device (K181034)	Comparison Results
System Resolution	≥ 1944 TVL	≥ 1944 TVL	Identical
Optical Resolution	MTF50=0.182 cy/px (or 0.182 line-pairs per pixel) or 130 lp/mm given the 1.4 x 1.4 μm size of the pixel	Lowest: 13.51 lp/mm Highest: 121.02 lp/mm	Different The optical resolution of the subject device is higher than the predicate device. This does not raise any different questions of safety and effectiveness.
Focus Mode	Manual Control: Auto Focus only	Manual Control: Auto focus only	Identical
Video Output	USB	USB	Identical
Image Geometric Distortion	<1% (±1)	0.3% to -3.24%	Different The geometric distortion in the image falls within the predicate device limits. This does not raise any different questions of safety and effectiveness.
Working Distance	30- 40 mm	5-50 mm	Different To observe the standard cervix size of 25 to 30 mm, the field of view provided within the 35 to 40 mm

Comparable Properties	Subject Device	Predicate Device (K181034)	Comparison Results
			working distance is adequately sufficient. This does not raise any different questions of safety and effectiveness.
Field of View (FoV)	At 35mm working distance ≥ 44 mm FoV(D): 63º DoV: 0º	At min. magnification ≥ 54.2 mm At max. magnification ≥ 5.87 mm	Different To observe the standard cervix size of 25 to 30 mm, the field of view provided within the 35 mm working distance is adequately sufficient. The field of view offered by the subject device encompasses a larger area than the standard cervix size. This does not raise any different questions of safety and effectiveness.
Depth of Field	At 35mm working distance 15.1 mm	At min. magnification 11.71 mm At max. magnification ≥ 1.86 mm	Different This subject device has a greater depth of field than the predicate device.

Comparable Properties	Subject Device	Predicate Device (K181034)	Comparison Results
			This does not raise any different questions of safety and effectiveness.
Freeze Function	Yes	Yes	Identical
Vascular Visualization	Green LED light	Green LED light	Identical
Cleaning	**Handle, Cable, and Tablet:** Surfaces disinfected with a disinfectant wipe. **Nozzle:** Cleaned and Disinfected	**Handle and Cord:** Surfaces disinfected with disinfectant wipe. **Probe:** High Level Disinfection	Identical
Radiation Safety	Does not emit any ionizing radiation	Does not emit any ionizing radiation	Identical

Discussion of similarities and differences:

The Smart Scope® CX and the Pocket Colposcope are intended for gynecological examinations, providing a portable means of magnified visualization to assist in detecting and monitoring abnormalities and infections of the external genitalia, vagina, and cervix. The Smart Scope® CX utilizes Net4Medix® software installed on a Smart tablet for visualization and annotation, while the Pocket Colposcope employs a laptop for this purpose. Both devices utilize both Green and white LED illumination.

The subject device operates within a recommended and fixed range of working distance (30 to 40 mm). The camera autofocuses at this minimum distance, leading to variations in calculation parameters compared to the predicate device working distance range (5-50 mm). All other parameters adjust according to the working distance. There are also differences in the illumination level, optical specification (e.g., depth of field, field of view), and magnification. These specifications are adequate for viewing the entire cervix, and the differences do not raise any different questions of safety and effectiveness.

Performance data

The following standards, guidance, and testing were used to evaluate performance of the Smart Scope® CX:

Electrical Safety and EMC:

1) IEC 60601-1:2005+AMD1:2012+AMD2:2020 CSV Consolidated version Medical electrical equipment - Part 1: General requirements for basic safety and essential performance.
2) IEC 60601-1-2:2014+AMD1:2020 CSV Consolidated version Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

Software:

1) Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices. Issued June 14, 2023.
2) IEC 62304 Edition 1.1 2015-06 CONSOLIDATED VERSION Medical device software - Software life cycle processes.

Cybersecurity:

1) Guidance for Industry and Food and Drug Administration Staff: Content of Premarket Submissions for Management of Cybersecurity. Issued September 27, 2023.

2) IEC 81001-5-1 Edition 1.0 2021-12 Health software and health IT systems safety, effectiveness and security - Part 5-1: Security - Activities in the product life cycle

Risk Management:

1) ISO 14971:2019 Medical devices — Application of risk management to medical devices.

Reprocessing:

1) Guidance for Industry and Food and Drug Administration staff: Reprocessing Medical Devices in Health Care Settings: Validation Method and Labelling. Issued March 17, 2015.

Labels & IFU:

1) ISO 15223-1 Fourth edition 2021-07 Medical devices - Symbols to be used with medical device labels, labelling, and information to be supplied - Part 1: General requirements.
2) ISO 20417 First edition 2021-04 Corrected version 2021-12 Medical devices — Information to be supplied by the manufacturer.

Performance:

1) ISO 8600-3:2019 Endoscopes — Medical endoscopes and endotherapy devices — Part 3: Determination of field of view and direction of view of endoscopes with optics.
2) ISO 8600-5:2020 Optics and photonics — Medical endoscopes and endotherapy devices — Part 5: Determination of optical resolution of rigid endoscopes with optics.
3) IEC 62471:2006 – Photobiological safety of lamps and lamp systems
4) Optical performance evaluation

Conclusion

The results of non-clinical testing demonstrate that the subject device is safe and effective as the predicate device to support a substantial equivalence determination.