September 5, 2024

DYNE Medical Group Inc.
% Kim Jong-Hyun
Chief Consultant
GMS Consulting
#B-612, 66 Chengcho-ro
Gyeonggi-do, Goyang-si 10543
KOREA, SOUTH

Re: K240203
Trade/Device Name: URUS System (DMG-SU100/URUS);
URUS System (DMG-SU100R/URUS);
URUS System (VP-100/Video Processor)
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FGB
Dated: January 25, 2024
Received: January 25, 2024

Dear Kim Jong-Hyun:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Mark R. Kreitz -S

for Mark J. Antonino, M.S.
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

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.

Submission Number *(if known)*

K240203

Device Name

URUS System (DMG-SU100/URUS);
URUS System (DMG-SU100R/URUS);
URUS System (VP-100/Video Processor)

Indications for Use *(Describe)*

URUS System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

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

DYNE
MEDICAL GROUP INC

510(k) Summary

[As Required by 21 CFR 807.92]

1. Date Prepared [21 CFR 807.92(a)(a)]

JAN 25, 2024

2. Submitter's Information [21 CFR 807.92(a)(1)]

- **Name of Manufacturer:** DYNE Medical Group Inc.
- **Address:** #1001-1011, 10F, 165, Gimpohangang 10-ro 133beon-gil, Gimpo-si, Gyeonggi-do, Republic of Korea 10071
- **Contact Name:** Young-Hoon Moon / Quality Manager
- **Telephone No.:** +82-31-8049-9013
- **Email Address:** yhmoon@dynemedical.com

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- **Trade Name:** URUS System
- **Common Name:** ureteroscope and accessories, flexible/rigid
- **Classification:**

Classification Name	ureteroscope and accessories, flexible/rigid
Classification Number	21 CFR 876.1500
Product Code	FGB
Device Class	II
Review Panel	Gastroenterology/Urology

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

Predicate Device

- **510(k) Number:** K181977
- **Applicant:** OUT Medical Inc.
- **Classification Name:** ureteroscope and accessories, flexible/rigid
- **Trade Name:** WiScope ™ Digital Endoscope System

5. Description of the Device [21 CFR 807.92(a)(4)]

The URUS System is a software-controlled single-use digital flexible ureteroscope system. That consist of the single-use digital flexible ureteroscope (DMG-SU100 / DMG-SU100R) and a video processing unit (VP-100). The URUS System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney.

- **URUS System Configurations:**

Model Name	Description
DMG-SU100	URUS Single-Use Digital Flexible Ureteroscope (Standard Deflection)
DMG-SU100R	URUS Single-Use Digital Flexible Ureteroscope (Reverse Deflection)
VP-100	URUS System Video Processor

6. Indications for use [21 CFR 807.92(a)(5)]

URUS System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(4)]

The table below presents comparisons between the subject device (URUS System) and the legally marketed predicate devices (K181977):

[Table 1. Comparison of Proposed Device to Predicate Device]

Item	Proposed Device	Predicate Device	Remark
K Number	K240203	K181977	-
Manufacturer	DYNE Medical Group Inc.	OUT Medical Inc.	-
Trade Name	URUS System	WiScope™ Digital Endoscope System	-
Classification Name	ureteroscope and accessories, flexible/rigid	ureteroscope and accessories, flexible/rigid	Same
Classification Regulation Number	21 CFR 876.1500	21 CFR 876.1500	Same
single-use	Single-Use	Single-Use	Same
Image System	Not including OS, monitor, and battery	Not including OS, monitor, and battery	Same
Environment of Use	healthcare facility/hospital	healthcare facility/hospital	Same
Intended Use	URUS System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.	WiScope™ Digital Endoscope System is intended to be used by physicians to access, visualize, and perform procedures in the urinary tract and the kidney. The instrument enables delivery and use of accessories such as biopsy forceps, laser fibers, graspers and retrieval baskets at a surgical site.	Same
Duration of Use	Single-Use, 4h	Single-Use	Same
Digital video technology	CMOS	CMOS	Same
Illumination	Fiber	LED	Different
Field of View (Diagonal)	85°	100°	Different
Depth of Field (㎜)	3 – 50 ㎜	2 - 50 ㎜	Different
Outer Shaft Diameter	9.5F	8.6Fr	Different

Overall length (㎜)	948 ㎜	905 ㎜	Different
Working Length (mm)	680	670	Different
Up/Down Deflection	UP: 270° DOWN: 270° 0°	UP: 275° DOWN: 275°	Different
Working Channel Diameter (Fr)	3.6Fr (1.2mm)	3.6Fr	Same
Direction of View	0°	0°	Same
Brightness Control	Yes	Yes	Same
White Balance	Yes	Yes	Same
Output Formats	USB/SD CARD/DVI/SDI/VGA	USB/AV/HDMI	Different
Image/Video Capture	YES	No	Different
Sterilization	Ethylene Oxide SAL: 10^-6	Ethylene Oxide SAL: 10^-6	Same
Packaging	packaged in a tray sealed by sterile barrier system	Ureteroscope is packaged in a tray which is sealed by sterile barrier	Same
Biologics	▪ Cytotoxicity ▪ Sensitization ▪ irritation: ▪ Acute systemic toxicity ▪ Pyrogenicity	▪ Cytotoxicity ▪ Sensitization ▪ irritation: ▪ Acute systemic toxicity ▪ Pyrogenicity	Same
Duration and type of contact	Limited (< 24 hours)	Limited (< 24 hours)	Same
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	Same

The comparison table shows that the subject device (URUS System) has the similar indications for use the predicate device. (i.e., for collection of physicians to access, visualize, and perform procedures in the urinary tract and the kidney.)

The subject and predicate devices have similar technological features, including Duration of Use, Digital video technology, Working Channel Diameter (Fr), Brightness Control, and White Balance.

However, as shown in the table above, there are different technological characteristics (Illumination, Field of View (Diagonal), Depth of Field, Outer Shaft Diameter, Overall length, Working Length (mm), Up/Down Deflection, Output Formats, Image/Video Capture) these differences do not make the subject device less safe and reliable, so the subject device fits for diagnostic use as the predicate device does. There are no significant differences in the technological characteristics of the subject device. All the differences between the subject and predicate device do not raise different questions of safety and effectiveness. Therefore, the test results confirmed that the no significant differences in the technological characteristics of the subject device.

8. PERFORMANCE DATA [21 CFR 807.92(b)(1)]

1) EMC, Wireless, and Electrical, Mechanical and Thermal Safety

The test results demonstrated that the proposed device complies with the following standards:

- Electrical Basic Safety and Essential Performance requirements in accordance with IEC 60601-1:2005/AMD2:2020
- Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2:2014+A1:2020
- Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems With IEC TS 60601-4-2:2024
- Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability in accordance with IEC 60601-1- 6:2010/AMD2:2020
- Medical electrical equipment - Part 2-18: Particular requirements for the basic safety and essential performance of endoscopic equipment with IEC 60601-2-18: 2009

2) Reprocessing, Sterility and Shelf-Life

- **Sterilization and shelf life testing**

The sterilization method has been validated to ISO 11135:2014, which has thereby determined the routine control and monitoring parameters.

EO/ECH residual test was performed according to ISO 10993-7:2008.

The shelf life (3 years) of the Single-Use Digital Flexible Ureteroscope is determined based on stability study which includes ageing test according to ASTM F1980-16, Standard Guide for Accelerated Aging of Sterile Barrier.

- **Package Validation**

Package validation was conducted according to ISO 11607-1:2019 and ISO 11607-2:2019, and visual inspection (ASTM F1886), seal strength (F88/F88M-21), dye penetration (ASTM F1929-15), Standard Practice for Performance Testing of Shipping Containers and Systems (ASTM D4169-22).

3) Software, Cybersecurity and Interoperability

The software was designed and developed according to IEC 62304 software development process and was verified and validated. According to the guidance, we evaluated the level of Basic level documentation by identifying safety-related characteristics for device documentation level.

- The software information is provided in accordance with FDA guidance: Content of Premarket Submissions for Device Software Functions: Guidance for Industry and Food and Drug Administration Staff', issued on JUNE 2023.
- Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submission

4) Mechanical and acoustic testing

All necessary performance testing has been conducted on the URUS System to assure substantial equivalence to the predicate devices and to demonstrate the device performs as intended. All testing was performed on test unit representative of finished devices.

The device passed the following tests:

- **Optical performance Bench Testing**

The URUS System was designed to comply with applicable parts of ISO 8600-1 standard. According to the ISO 8600 standard, we test following performance items:

- Field of View	- Depth of Field
- Resolution	- Distortion
- IIU (Image Intensity Uniformity)	- SNR/DR

- **Performance Bench Testing**

The URUS System was designed to comply with applicable parts of ISO 8600-1 standard. According to the ISO 8600 standard, we test following performance items:

- Outer Shaft Diameter	- Overall length
- Working length	- Working Channel Diameter
- Up/Down Deflection	- Direction of View
- Depth of Field	- Tip Column Strength
- Lever Force	- Tip to Shaft Tensile Strength
- Accessory port	- Brightness Control
- White balance	- Connections tensile strength
- Torque and Leakage	- Flow rate and pressure
- Torque strength	- fatigue
- Bending path	- Leakage

5) Biocompatibility

The biocompatibility evaluation for the patient contacting components of the Single-Use Digital Flexible Ureteroscope performed according to ISO 10993-1:2018 and FDA Guidance. The following tests were conducted based contact category of "externally communicating device contacting tissue/bone/dentin" with a contact duration of "Limited (< 24 hours):

- Cytotoxicity	ISO 10993-5:2009
- Sensitization	ISO 10993-10:2021
- irritation:	ISO 10993-23:2021
- Acute systemic toxicity	ISO 10993-11:2017
- Pyrogenicity	ISO 10993-11:2017

6) Clinical Test Summary:

The subject of this premarket submission did not require clinical studies were considered necessary and performed.

9. Conclusion [21 CFR 807.92(b)(3)]

In according with the Federal Food & Drug and cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification DTNE Medical Group Inc., concludes that the URUS System is substantially equivalent in safety and effectiveness to the predicate devices as described herein.