June 12, 2026

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

Re: K252933
Trade/Device Name: DYNE PORT
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: ODC
Dated: May 12, 2026
Received: May 12, 2026

Dear Jonghyeon Kim:

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: The Center for Devices and Radiological Health (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, the Food and Drug Administration (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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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 J. ANTONINO -S

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.

510(k) Number *(if known)*
K252933

Device Name
DYNE PORT

Indications for Use *(Describe)*
This device is intended to resist the backflow of fluid around an instrument inserted through the working channel of a ureteroscope, cystoscope, or other endoscope.

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

[As Required by 21 CFR 807.92]

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

Aug 29, 2025

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

- **Name of Manufacturer:** DYNE Medical Group Inc.
- **Address:** #1001-1013, #1015-1016, #1024-1025, 10F, 165, Gimpohangang 10-ro 133beon-gil
- **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:** DYNE PORT
- **Model Name:** SP-100 / YP-100
- **Classification:**

Common Name	Endoscope Channel Accessory
Classification Name	Endoscope and Accessories
Classification Number	21 CFR 876.1500
Product Code	ODC
Device Class	II
Classification 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:** K173105
- **Applicant:** Cook Incorporated
- **Classification Name:** Endoscope Channel Accessory
- **Trade Name:** Tuohy-Borst Adapter

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

The DYNE PORT is a single-use, sterile accessory for endoscopes, available in two configurations: a straight type (SP-100) and a Y-port type (YP-100). The device features a Luer connector on its distal end for attachment to an endoscope's accessory port.

The DYNE PORT is constructed from its primary components: an Adjustment Cap, a main body, and a Luer Connector. The main body is designated as the Single Port (SP-100) or the Dual Port (YP-100). The device is designed to secure the position of an instrument inserted through the device, and simultaneously prevent the leakage of irrigation fluid.

The YP-100 is an alternate design that incorporates a Y-shaped body with a side port for additional access. A distinguishing feature of the YP-100 is a Position Adjustment Lever, which allows for fine control of the instrument's depth after it has been secured by the Adjustment Cap.

The DYNE PORT is sterilized using Ethylene Oxide (EO) gas and is intended for single use only.

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

This device is intended to resist the backflow of fluid around an instrument inserted through the working channel of a ureteroscope, cystoscope, or other endoscope.

7. Technological Characteristics (Equivalence to Predicate Device) [21 CFR 807.92(a)(6)]

The table below presents comparisons between the subject device (DYNE PORT) and the legally marketed predicate devices (K173105):

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

	Proposed Device	Predicate Device	Remark
K Number		K173105	-
Manufacturer	DYNE Medical Group Inc.	Cook Incorporated	-
Trade Name	DYNE PORT	Tuohy-Borst Adapter	-
Model Name	SP-100, YP-100	TBA-6, TBAYR-6	-
Product code	ODC; Endoscope Channel Accessory	ODC; Endoscope Channel Accessory	Same
Classification Regulation Number	21 CFR §876.1500	21 CFR 876.1500	Same
Device class	II	II	Same
Usage	Single-Use	Single-Use	Same

Environment of Use	healthcare facility/hospital	healthcare facility/hospital	Same
Intended Use	This device is intended to resist the backflow of fluid around an instrument inserted through the working channel of a ureteroscope, cystoscope, or other endoscope.	This device is intended to resist the backflow of fluid around an instrument inserted through the working channel of a ureteroscope, cystoscope, or other endoscope.	Same
Accepts Instrumentation Fr (Working channel Inner diameter)	9.0 FR (3.0 mm)	3.0-6.0 FR	Different
Energy Used/Delivered	None	None	
Sterilization	Ethylene Oxide (SAL: 10^{-6})	Ethylene Oxide	Same
Shelf life	3 years	3 years	Same
Biologics	Performed for the items below: ▪ Cytotoxicity ▪ Skin sensitization ▪ Intracutaneous reactivity ▪ Acute systemic toxicity ▪ Pyrogen	Performed	Same
Duration and type of contact	Limited (< 24 hours)	Limited (< 24 hours)	Same
Material	Polycarbonate, Polypropylene, TPE, Silicone	ACETAL, polycarbonate, polyethylene	Different
Label and Labeling	Meet FDA's Requirements	Meet FDA's Requirements	

The comparison table shows that the subject device, the DYNE PORT, has the same Indications for Use as the predicate device, Cook Incorporated's Tuohy-Borst Adapter. Both devices share the same intended use, and also share the same device class, single-use designation, and duration of patient contact.

Although the devices have some different technological characteristics, primarily in accepted instrumentation size, shelf life, and the materials of construction. Characteristics of the subject devices that differ from the predicate devices are supported by testing and analysis.

8. Performance Data

The following testing was performed in order to demonstrate that the proposed DYNE PORT met applicable design and performance requirements.

- Biocompatibility
- Sterilization
- Leakage
- Device Compatibility and Integrity
- Accelerated Age

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 DYNE Medical Group Inc., concludes that the DYNE PORT is substantially equivalent in safety and effectiveness to the predicate devices as described herein.