January 31, 2025

Dornier MedTech America
John Hoffer
Vice President Quality Assurance and Regulatory Affairs
1155 Roberts Blvd
Suite 100
Kennesaw, Georgia 30144

Re: K243820
Trade/Device Name: Hoover Negative Pressure Access Sheath (Hoover)
(Hoover Model #'s IVX-NS-1040, IVX-NS-1050, IVX-NS-1140, IVX-NS-1150, IVX-NS-1240, IVX-NS-1250
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FED, FAJ, FGA
Received: December 12, 2024

Dear John Hoffer:

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)*

K243820

Device Name

Hoover Negative Pressure Access Sheath (Hoover) (Hoover Model #'s IVX-NS-1040, IVX-NS-1050, IVX-NS-1140, IVX-NS-1150, IVX-NS-1240, IVX-NS-1250)

Indications for Use *(Describe)*

The Dornier Hoover Negative Pressure Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures.

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) #: **510(k) Summary** Prepared on: 2024-12-12

Contact Details 21 CFR 807.92(a)(1)

Applicant Name	Dornier MedTech America
Applicant Address	1155 Roberts blvd Suite 100 Kennesaw ga 30144 United States
Applicant Contact Telephone	770-514-6163
Applicant Contact	Mr. John Hoffer
Applicant Contact Email	jhoffer@dornier.com

Device Name 21 CFR 807.92(a)(2)

Device Trade Name	Hoover Negative Pressure Access Sheath (Hoover) (Hoover Model #'s IVX-NS-1040, IVX-NS-1050, IVX-NS-1140, IVX-NS-1150, IVX-NS-1240, IVX-NS-1250)
Common Name	Endoscopic Access Overtube, Gastroenterology-Urology
Classification Name	Endoscope and Accessories
Regulation Number	21 CFR § 876.1500
Product Code(s)	FED, FAJ,FGA

Legally Marketed Predicate Devices 21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K161110	ClearPetra Ureteral Access Sheath	FED

Device Description Summary 21 CFR 807.92(a)(4)

The Dornier Hoover Negative Pressure Access Sheath is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures. It is for the passage of endoscopes and other urological devices for Ureteroscopy and used for the treatment of stones and for the removal of foreign bodies in the urinary tract.

The packaged product includes a Hydrophilic-coated Dilator with a locking mechanism and a Hydrophilic- coated guide sheath with joint.
The guide sheath is fitted with a Y connector on the proximal end. The Y connector is bifurcated: straight tube and oblique tube. One segment of the Y connector is straight and is contiguous with the sheath. The other is constructed in an oblique angle with a longitudinal pressure control vent. The oblique tube is to be connected to a negative pressure aspirator with clear tube or alternatively, connected to a specimen collector then onto a negative pressure aspirator, then to collect stones or foreign bodies during the endoscopic procedure.
A dilator is included for the insertion of the sheath. The dilator is radiopaque and is fitted with a hand buckle on the proximal end. The dilator can be locked to the proximal end of the straight tube using a locking mechanism.

The Dornier Hoover Negative Pressure Access Sheath is reinforced with a stainless-steel coil, constructed of a medical grade thermoplastic elastomer. All colorants used are compliant with FDA standards.
The device is offered of inner diameter in French size 10Fr, 11Fr, 12Fr and length 40cm, 50cm. The device is supplied sterile and intended for single use only.

The Dornier Hoover Negative Pressure Access Sheath has six different models. The structural composition and materials of the different models are identical. The only difference is in dimension including inner diameter, outer diameter, and length.

Model	Length(mm)	Inner diameter	Outer diameter
IVX-NS-1040	400	3.30(10Fr)	3.96(12Fr)
IVX-NS-1050	500	3.30(10Fr)	3.96(12Fr)
IVX-NS-1140	400	3.66(11Fr)	4.32(13Fr)
IVX-NS-1150	500	3.66(11Fr)	4.32(13Fr)
IVX-NS-1240	400	3.96(12Fr)	4.62(14Fr)
IVX-NS-1250	500	3.96(12Fr)	4.62(14Fr)

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

The Dornier Hoover Negative Pressure Access Sheath is used to establish a conduit during endoscopic urological procedures facilitating the passage of endoscopes and other instruments into the urinary tract. It is designed to establish a conduit for the treatment of urinary stones or other urinary diseases during the endoscopic procedures.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The predicate device and the device subject to this submission have the same indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The Dornier Hoover Negative Pressure Access Sheath has essentially the same technological characteristics as the predicate device. Both devices are comparable in their material composition, design, their mechanical characteristics and their use. As noted above, the indication for use are the same for both devices. The devices are both single use and are sterilized with ETO.
Based on the results from the comparative testing as described in the attachment, although there are some slight differences in characteristics between the subject and predicate product, we conclude the products are substantially equivalent.

The predicate device has not been subject to a design-related recall.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The following performance bench testing was conducted to verify that the performance of the Dornier Hoover Negative Pressure Access Sheath is substantially equivalent to the predicate device, and that the device will perform as intended.

General performance testing including:

- Connection Strengths
- Coefficients of Friction
- Dimensional Analysis
- Fluid Leakage

Testing data and results are included in this submission and demonstrate that the Dornier Hoover Negative Pressure Access Sheath meets all the pre-determined testing and acceptance criteria.

The following Biocompatibility testing was performed:

- Cytotoxicity as per ISO 10993-5:2009
- Irritation as per ISO 10993-23:2021
- Sensitization as per ISO 10993-10:2021

Biocompatibility testing reports are included in this submission and demonstrate that the device components that are in contact with the patient are biocompatible.

Sterilization by ethylene oxide has been validated for Dornier Hoover Negative Pressure Access Sheath in accordance with EN ISO 11135:2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices

The nonclinical performance bench testing of the device demonstrates the Dornier Hoover Negative Pressure Access Sheath meets its design requirements. The testing also shows the subject device is substantially equivalent in these characteristics to the predicate device.