January 17, 2025

AMB Medtec
℅ Michael Nilo
President and Principal Consultant
Nilo Medical Consulting Group LLC
3706 Butler St, Suite #313
Pittsburgh, Pennsylvania 15201

Re: K242336
Trade/Device Name: hygh-tec drainage II
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: December 18, 2024
Received: December 18, 2024

Dear Michael Nilo:

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,

Anthony Lee -S

Anthony Lee, Ph.D., M.B.A.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant 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)*
K242336

Device Name
hygh-tec drainage II

Indications for Use *(Describe)*
The hygh-tec drainage II is a fecal management system that is intended for continuous, trans-anal drainage and collection of liquid or semi-liquid stools and to provide access for the administration of medications. The device is not intended for use on pediatric patients.

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) #: K242336

510(k) Summary

Prepared on: 2024-12-18

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	AMB Medtec
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Correspondent Contact Telephone	717-421-4396
Correspondent Contact	Michael Nilo, President and Principal Consultant
Correspondent Contact Email	michael.nilo@nilomedicalconsulting.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	hygh-tec drainage II
Common Name	Gastrointestinal tube and accessories
Classification Name	Gastrointestinal Tube And Accessories
Regulation Number	876.5980
Product Code(s)	KNT

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K221400	hygh-tec® drainage	KNT

Device Description Summary

21 CFR 807.92(a)(4)

The hygh-tec drainage II is a fecal drainage system that is comprised of a stool drainage tool, a stool collection bag, and an inflating syringe. The device is used by healthcare professionals in a professional healthcare environment for continuous trans-anal drainage and collection of stools. The stool drainage tool is placed trans-anally within the patient while a liquid is infused within a specialized port to irrigate the rectum. The organic matter then progresses through the drainage tube where it is eventually stored in the collection bag for evaluation or disposal. Along with stool drainage, the hygh-tec drainage II system can be used for the administration of medication that would be prescribed by physicians.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The hygh-tec drainage II is a fecal management system that is intended for continuous, trans-anal drainage and collection of liquid or semi-liquid stools and to provide access for the administration of medications. The device is not intended for use on pediatric

patients.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indications for use for both the Hygh-Tec drainage II and the predicate device are identical.

Technological Comparison

21 CFR 807.92(a)(6)

The design and the principle of operation are the same between the Hygh-Tec drainage II and the Hygh-Tec® Basic-Plus. The only difference is in the material used for the drainage tube. The subject device uses a three-layer extruded tube made of TPU-EVOH-TPU while the predicate drainage tube is made of PVC.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

The following tests were performed to test the device for substantial equivalence and all tests passed:
ISO 10993-5:2009
ISO 10993-10:2021
ISO 10993-23:2021
Tensile Strength Testing