February 9, 2023

Creative Balloons GmbH
Michael Nilo
President and Principal Consultant
Nilo Medical Consulting Group
3491 Denny St.
Pittsburgh, PA 15201

Re: K221400
Trade/Device Name: hygh-tec drainage
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: January 10, 2023
Received: January 11, 2023

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 (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 located 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.

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

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

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Je Hi An, Ph.D.
Assistant Director
DHT3A: Division of Renal, Gastrointestinal,
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OHT3: Office of GastroRenal, ObGyn,
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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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K221400

Device Name
hygh-tec drainage

Indications for Use *(Describe)*

The hygh-tec drainage 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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Prepared: January 10, 2023

I. SUBMITTER

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II. DEVICE

Name of Device:	hygh-tec drainage
Common/Usual Name:	Fecal Management System
Regulation Numbers:	21 CFR 876.5980
Regulation Name:	Gastrointestinal tubes and accessories
Regulatory Class:	II
Product Codes:	KNT, Tubes, Gastrointestinal (And Accessories)

III. PREDICATE DEVICE

Primary Predicate	Flexi-Seal® SIGNAL™ Fecal Management System, K150350

IV. DEVICE DESCRIPTION

The hygh-tec drainage is sold as a kit to include a main catheter component, collection bag, inflation syringe, and closure strap. The catheter component consists of a retaining and sealing balloon element, a trans-anal segment, drainage shaft, an elastically deformable tip, a colored positioning ring, a stool irrigation tube, an irrigation line, and an air filling line.

V. INDICATIONS FOR USE

The hygh-tec drainage 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

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following table identifies technological characteristics shared between the predicate and subject device:

Table 1: Comparison of Technological Characteristics with Predicate Device

Parameter	**Subject Device** **hygh-tec drainage** **(K221400)**	**Predicate** **FlexiSeal** **Fecal Management System** **(K150350)**
FDA Product Code	KNT	KNT
FDA Classification Regulation	21 CFR 876.5980	21 CFR 876.5980

Classification	Class II	Class II
Intended use	The hygh-tec drainage 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.	To manage fecal incontinence through the collection of liquid to semi liquid stool to provide access to administer medications
Functional Configuration	A head unit with collapsible wave-shaped hose section enveloped with a sealed balloon segment on the distal end secured in the rectum and proximal end connected to a collection bag	Collapsible catheter with distal end secured in the rectum and proximal end connected to a collection bag
Retention Feature	Low pressure contoured cuff for patients anatomy and facilitating sealing.	Soft annular Balloon
Balloon material	Thermoplastic Polyurethane (TPU)	Silicone rubber (Elastomere)
Inflation management	Sealed air-filled balloon (low-pressure Cuff)	Sealed water filled balloon
Retention balloon inflation medium	Air (85ml)	Water/saline (45ml)
Catheter tube length	1730 mm	1550mm – 1670mm
Length of trans-anal area	~ 49 mm (length of the trans-anal balloon segment)	~ 7 cm (from Balloon to black Position marking)

Position marking	Yes (Yellow ring)	Yes (Black marking on catheter tube)
Inflation and irrigation port connections	Luer	Luer
Inflation lines	1	2
Irrigation lines	1	1
Sampling port	Closable snap seal for catheter syringe access – natural color	Closeable snap seal for catheter syringe access – natural color
Collection bag configuration	Disposable with vent and connector	Disposable with integrated cap and vent
Collection bag size	2 litre	1 litre
Method of bed connection	Hanging strap and a hook-on bag connector	Hanging Strap on bag connector
Flow stop mechanism	External Strap	External Tube Strap
Sterility status	Non-sterile	Non-sterile
Max Usage of Device	29 days	29 days
Medication Delivery	Yes	Yes
Packaging	Thermoformed plastic clamshell	Thermoformed plastic clamshell

The following differences between the subject and predicate device were evaluated to support a substantial equivalence determination:

- The filling medium of the retention balloons is different (air vs. water)

- The materials utilized in the subject and predicate device are different.

VII. PERFORMANCE TESTING

The following performance testing was conducted to support substantial equivalence:

Performance Testing

The following design verification activities have been performed to ensure the appropriate functionality of the system:

- Shelf-Life Testing
- Simulation of Transport Loads
- Leak Tightness Testing
- Retention Testing
- Overfilling Testing
- Flow Rate Measurement Testing

Biocompatibility

Biocompatibility testing was conducted and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process'."

VIII. CONCLUSIONS

The differences that exist between the hygh-tec drainage and its predicate do not raise different questions of safety or effectiveness. The results of performance and biocompatibility testing demonstrate that the hygh-tec drainage will perform safely as intended and support a determination of substantial equivalence to the predicate device which is marketed for the same intended use.