October 24, 2018

Bionix Development Corporation
James Huttner
Vice President, Product Development
5154 Enterprise Blvd.
Toledo, Ohio 43612

Re: K180605
Trade/Device Name: GastroFlush
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube And Accessories
Regulatory Class: Class II
Product Code: KNT, PIF
Dated: September 12, 2018
Received: September 18, 2018

Dear James Huttner:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Daniel G. Walter Jr -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180605

Device Name
GastroFlush

Indications for Use *(Describe)*
GastroFlush is indicated for use in clearing occlusions/clogs from enteral feeding tubes placed for nutrition and/or decompression in adult or adolescent patients that have tube size 8Fr-24Fr and tube length no longer than 42 inches.

It is intended to be used by or under the direction of a licensed physician.

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:

Corporate Office
5154 Enterprise Blvd., Toledo, Ohio 43612
Phone 419.727.8421 • Fax 419.727.8426

October 12, 2018

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92

1. **Submitter Information:**

   a. Applicant: Bionix Development Corporation
   5154 Enterprise Blvd.
   Toledo, Ohio 43612

   b. Contact: James Huttner M.D., Ph.D.
   Vice President, New Product Development
   Phone: (419) 727-8421
   Fax: (419) 727-4430
   Email: jhuttner@bionix.com

2. **Device Name:**

   a. **Trade Name:** GastroFlush

   b. **Common Name:** Enteral Tube Un-Clogger

   c. **Classification Name:** Gastrointestinal tube and accessories

   d. **Regulation Numer:** 876.5980

   e. **Product Code(s)** : KNT; PIF

3. Indications for Use:

GastroFlush is indicated for use in clearing occlusions/clogs from enteral feeding tubes placed for nutrition and/or decompression in adult or adolescent patients that have tube size 8Fr-24Fr and tube length no longer than 42 inches.

It is intended to be used by or under the direction of a licensed physician.

4. Substantial Equivalence Device(s):

The GastroFlush enteral tube un-clogger is similar in intended use and function to the following devices used to unclog plugged enteral tubes such as G-tubes (gastrostomy tubes), J-tubes (jejunostomy tubes), nasogastric feeding tubes, and nasogastric sumps or decompression tubes:

a. TubeClear In-Patient Tube Clearing System, manufactured and legally marketed by Actuated Medical, Bellefonte, PA. This device is listed under regulation number 876.5980, Tubes, Gastrointestinal and Accessories, and is classified as a Class II device. This device has been cleared by the FDA under K121571.

b. DeClogger, manufactured and legally marketed by Bionix Development Corporation, Toledo, Ohio. This device is listed under regulation number 876.5980, Tubes, Gastrointestinal and Accessories, and is classified as a Class II device. This device has been cleared by the FDA under K905164.

5. Device Description

The GastroFlush device uses a pulsatile stream of pressurized water to gently dislodge and flush clogs from obstructed G-tubes, J-tubes, NG tubes and other tubes placed for the purposes of enteral nutrition and/or gastrointestinal decompression in the clinical or home setting. A series of connected one-way valves is used to ensure that the pressurized water flows in only the correct direction. Pressure relief valves with specified “cracking pressure” are used to ensure that overpressure of the system is avoided. Lastly, specialty connectors including the use of the new ENFit enteral feeding tube connectors conforming to ISO 80369-3 ensure against the inadvertent misconnection of the GastroFlush device to the clogged enteral tube, or the use of Luer syringes and/or similar devices in the attempt to unclog the enteral tube.

A schematic representation of the GastroFlush device is shown below to better describe the directional water flow of the device.

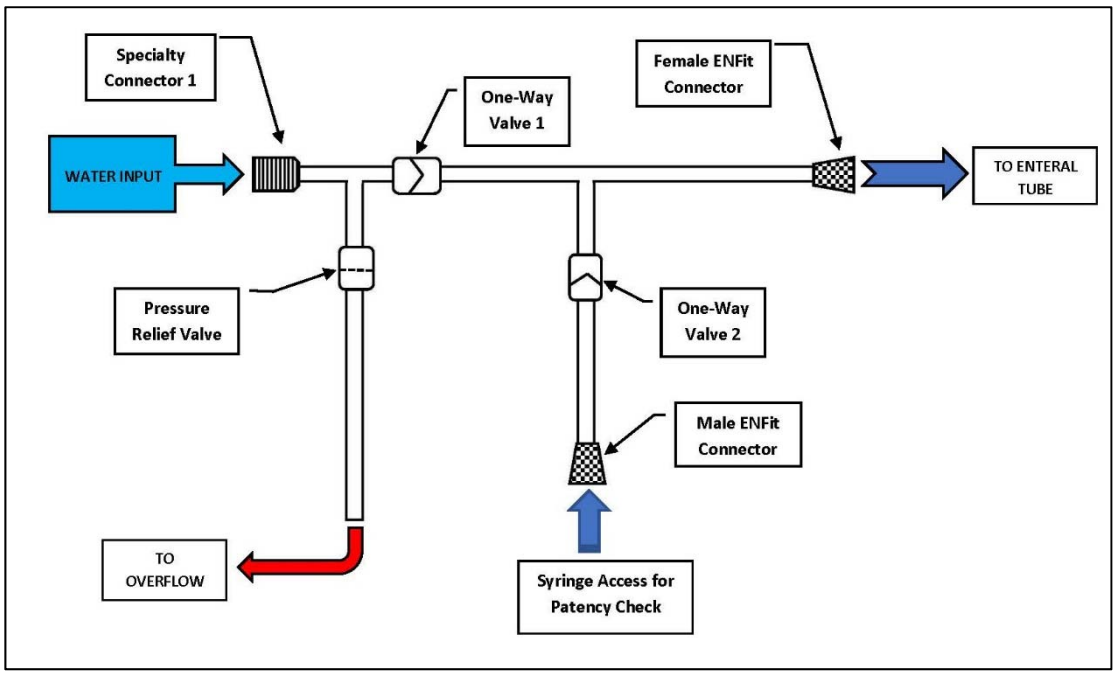

Figure 1
Schematic Drawing Showing GastroFlush Water Flow

From the diagram, water flows in a unidirectional fashion through the GastroFlush and into the connected clogged enteral tube. Directional water flow is maintained using a one-way valve (Valve 1) that permits water flow only towards the enteral tube and prevents back-flow of potentially contaminated water.

To prevent potentially hazardous high-pressure that could result from attempts to clear a clogged enteral tube, a safety outlet conduit is provided with an integrated pressure relief valve. The cracking pressure of this valve is set high enough to allow sufficient pressure to unclog the enteral tube, but well below the burst pressure of the enteral tube, the GastroFlush tubing, or any of its components. Water exiting through the pressure relief valve is directed to an overflow basin.

To test the enteral tube for patency after performing the de-clogging procedure, a port is provided to allow a flush of water from a syringe. A second one-way valve (Valve 2) maintains unidirectional flow through this tube and prevents back-flow and/or high-pressure water exiting this port.

Specialty connectors have been used throughout the GastroFlush to ensure proper directional connection to the water delivery unit. In accordance with the new ISO standard 80369-3, ENFit connectors are used to connect the GastroFlush device to the enteral tube, and to allow an ISO

80369-3 ENFit compatible syringe to connect to the patency check port. This prevents the inadvertent connection of a syringe with a Luer or other fitting to the GastroFlush.

A pressurized pulsatile stream of water is supplied to the GastroFlush by a standard jet lavage unit. A specialty connector (Specialty Connector 1) is used to ensure proper connection of the GastroFlush to the water delivery unit, as each jet lavage model has a different, proprietary connector. This connector (Specialty Connector 1) is of a type not compatible with ENFit, Luer, or other commonly used medical connectors.

A 2-D CAD drawing of the GastroFlush is shown in Figure 2, and the various components are again labeled.

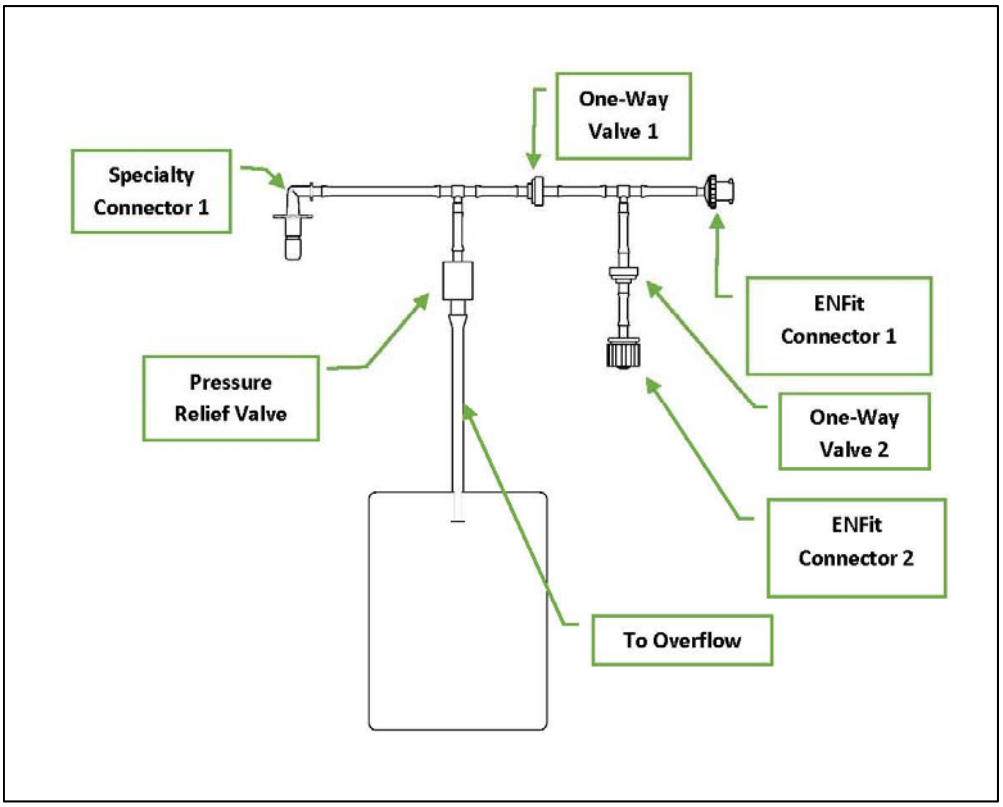

Figure 2
GastroFlush Assembly

6. Comparison to Predicate Devices:

The GastroFlush enteral tube un-clogger is similar in function and intended use to the TubeClear In-Patient Tube Clearing System, manufactured and legally marketed by Actuated Medical, Bellefonte, PA. The GastroFlush is also similar in function and intended use to the DeClogger, manufactured and legally marketed by Bionix Development Corporation, Toledo, Ohio.

The following table summarizes the comparison of Bionix Development Corporation GastroFlush to these predicate devices:

Attribute	TubeClear In-Patient Tube Clearing System	DeClogger	GastroFlush
Intended Use	Clear Occlusions from Feeding and Decompression Tubes	Clear Occlusions from Feeding and Decompression Tubes	Clear Occlusions from Feeding and Decompression Tubes
Portion of Device Impacting Clog	Clearing Stem Wire Tip	DeClogger Screw Tip	Water Jet
Mechanism of Clog Disruption	Linear Reciprocating Motion of Clearing Stem Wire Tip	Twisting Motion of Screw Tip	Pulsation of Water Jet
Composition of Declogging Mechanism	Metal Wire	Molded Plastic	Water
Power System	Electric Motor Creates Reciprocating Motion	Manual Twisting Motion of DeClogger Tip	Separate Water Pump Creates Pulsatile Water Stream
Single Patient Use	Yes	Yes	Yes

Table 1
Comparison of Substantial Equivalence

7. Performance Standards

a. This device meets Recognized Consensus Standard: AAMI/ANSI ID54:1996/(R) 2012, "Enteral feeding set adapters and connectors".
b. The following Industry Guidance Document has also been considered in the design of this device: "Safety Considerations to Mitigate the Risks of Misconnections with Small-bore Connectors Intended for Enteral Applications", document issued on February 11, 2015.
c. ISO Standard 80369 (ENFit Connectors).

8. Bench Testing:

The GastroFlush enteral Tube un-clogger was subjected to testing for safety and efficacy as described in the section titled "Bench Testing". Properties tested were:

a. Tube Clearance Testing
b. Leak-Free Pressure Testing
c. Overpressure Valve Testing

The results of these tests may be found in the section "**Performance Testing—Bench**". These results are summarized below.

a. **Tube Clearance Testing.** Testing was performed on the GastroFlush device's ability to clear an in-vitro occlusion from enteral feeding tubes designated as "worst case" examples, as defined through discussions with FDA reviewers. These included examples of the smallest diameter/longest tubes and the largest diameter/longest tubes intended to be used with the GastroFlush. Testing rationale and protocol was chosen to allow determination of results at the 95% C/R (Confidence/Reliability) level for an attribute data test of Risk Level 1. Accordingly, 30 enteral feeding tubes from each group were chosen for testing.

   Results of Tube Clearance Testing showed no failures in the ability of the GastroFlush to clear in-vitro occlusions from enteral feeding tubes in "worst case" scenarios at the 95% C/R level. Mean time to tube clearance was 2.20 seconds (smallest diameter/longest tube), and 1.79 seconds (largest diameter/longest tube).

   These results show that the GastroFlush device will successfully un-clog occluded enteral feeding tubes at the 95% Confidence/Reliability level.

b. **Leak-Free Pressure Testing.** Pressure testing was performed to ensure leak-free performance of the GastroFlush enteral tube un-clogger. Testing rationale and protocol was chosen to allow determination of results at the 95% C/R level for an attribute data test of Risk Level 1. Accordingly, 30 enteral feeding tubes from each group were chosen for testing.

   Results of Leak-Free Pressure Testing showed no leakage in any of the GastroFlush/enteral tube assemblies at pressures up to 30 PSI (twice the opening pressure of the overpressure valve).

   These results show that the GastroFlush device will operate leak-free during use at the 95% Confidence/Reliability level.

c. **Overpressure Valve Testing.** Testing was performed to evaluate the ability of the overpressure valve used in the GastroFlush to properly open at the indicated opening pressure of 12.5 PSI, and to prevent system operating pressure from rising over 15 PSI.

Testing rationale and protocol was chosen to allow determination of results at the 95% C/R level for a variable data test of Risk Level 1. Accordingly, 15 sample valves from the production lot were randomly selected to undergo Overpressure Valve Testing.

Results of Overpressure Valve Testing showed the mean opening pressure of the overpressure valves to be 12.71 PSI (SD = 0.34). These results show that the overpressure valves used in the construction of the GastroFlush device will open within specifications and below 15 PSI at the 95% Confidence/Reliability level.

9. Clinical Testing:

No clinical testing was performed on the GastroFlush Enteral Tube Un-Clogger from Bionix Development Corporation.

10. Human Factors Validation Testing:

Human factors validation testing was performed to identify any design or procedural elements that might interfere with proper and safe use of the device. These results are tabulated in the section "Human Factors Validation Testing" and are summarized below.

11. Conclusion:

These results show that the GastroFlush enteral tube un-clogger from Bionix Development Corporation will perform safely and adequately for the intended use to clear occlusions and clogs from enteral tubes placed for the purposes of nutrition and/or decompression in the clinical or home setting.