December 4, 2020

Actuated Medical, Inc.
Douglas Dillon
Director, Quality Assurance & Regulatory Affairs
310 Rolling Ridge Dr.
Bellefonte, PA 16823

Re: K200646
Trade/Device Name: TubeClear System
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and accessories
Regulatory Class: Class II
Product Code: KNT
Dated: March 11, 2020
Received: November 5, 2020

Dear Douglas Dillon:

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,

Shanil P. Haugen, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200646

Device Name
TubeClear System

Indications for Use *(Describe)*
TubeClear Clearing Stem Model GJ-1422 is indicated for use ONLY and SOLELY in clearing occlusions/clogs in adults that have the following Tube type and size (French and length).
+ GJ-1422, for G-Jet®, MIC®, and MIC-KEY® Gastro-jejunostomy tubes that are size 14-22 Fr and have a jejunal length of 15-45 cm (6-18 in).

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.

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510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR 807.92.

510(k) Number: K200646

Applicant Information

Date Prepared: November 4, 2020

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Device Information

Trade/Device Name:	TubeClear System
Common Name:	In Patient Tube Clearing System
Regulatory Class:	Class II
Classification:	KNT
Regulation Number:	21 C.F.R. 876.5980
Regulation Name:	Gastrointestinal Tubes and Accessories

Predicate Device

The legally marketed device to which substantial equivalence is being claimed is as follows:

510(k) Number	Trade Name	Manufacturer
K163092	TubeClear System	Actuated Medical, Inc.

Device Description

The TubeClear System is comprised of a reusable Control Box and a single use Clearing Stem. Control Box Model 101 is used to actuate all Clearing Stem models. The Clearing Stem for the predicate device is TubeClear Clearing Stem Model TC-0608 (TC-0608). The Clearing Stem for the subject device is TubeClear Clearing Stem Model GJ-1422 (GJ-1422). GJ-1422 is connected to the Control Box. The Operator then coats GJ-1422 with Coconut Oil and manually inserts it into the gastro-jejunostomy (GJ) tube (Tube) and directs the progression of the Clearing Stem inside the Tube. The Control Box actuates the Clearing Stem Wire. The Clearing Stem Wire Tip mechanically clears the occlusion to restore Tube patency. Sixteen (16) Clearing Stem Models are currently marketed to accommodate different types, sizes, and materials of feeding tubes. This submission adds a seventeenth (17^{th}) Clearing Stem model (GJ-1422) for use in a specific set of gastro-jejunostomy (GJ) tubes. Use of TubeClear Clearing Stem Model GJ-1422 requires coating the Clearing Stem with Coconut Oil prior to introduction into a patient's feeding tube.

Intended Use

The TubeClear System is intended to clear occlusions/clogs in Feeding and Decompression Tubes.

Indications for Use of GJ-1422

TubeClear Clearing Stem Model GJ-1422 is indicated for use **ONLY** and **SOLELY** in clearing occlusions/clogs in adults that have the following Tube type and size (French and length).

- GJ-1422, for G-Jet®, MIC®, and MIC-KEY® Gastro-jejunostomy tubes that are size 14-22 Fr and have a jejunal length of 15-45 cm (6-18 in).

Technological Characteristics

The technological characteristics of TubeClear Clearing Stem Model GJ-1422 are mostly identical to TubeClear Clearing Stem Model TC-0608. The differences are:

- Coconut Oil: GJ-1422 requires the application of Coconut Oil to the Clearing Stem prior to insertion, while applying a water-based medical lubricant is optional for TubeClear Clearing Stem Model TC-0608.
- Indications: GJ-1422 is indicated for a specific set of gastro-jejunostomy (GJ) tubes for which TC-0608 is not indicated.
- Stem Label: GJ-1422 has a blue Stem Label to visually differentiate it from TC-0608, which has a white Stem Label. This does not affect the safety nor the functionality of the device, as it is not a patient-contacting component and is only used to convey intellectual property information and to differentiate the models.

The design and function of all remaining components are identical. Both models consist of a Wire enclosed in a Sheath, a Depth Limiting Component, and a Magnet which connects to the reusable Control Box. Once the Clearing Stem is inserted into the Tube, the Control Box actuates the Clearing Stem in a backward and forward movement to physically break up clog contents in a Tube.

Non-Clinical Performance Data

AMI reviewed the testing performed in support of the predicate model and repeated those tests where risk analysis suggested potential risk due to the use of the Coconut Oil and the different Indications for Use. Clearing Stem Removal Forces, Benchtop Efficacy, Feeding Tube Integrity and Flow Rate testing (following use of Clearing Stem with Coconut Oil) was performed. In addition, USP monograph testing (USP 42) and a literature-based toxicological risk assessment was conducted to provide evidence that the addition of the Coconut Oil does not present unacceptable adverse risks to the patients.

The following brief discussion of these tests and the conclusions drawn demonstrate the substantial equivalence of GJ-1422 to TC-0608 by establishing that the proposed Clearing Stem is substantially equivalent to TC-0608.

Clearing Stem Removal Forces and Benchtop Efficacy:

Benchtop Efficacy: Worst-case artificial clogs were placed in series of indicated Tubes including 14Fr-18Fr, silicone, G-Jet® Button Low profile Gastric-Jejunal (GJ) enteral feeding tubes, 14Fr-22Fr, silicone, MIC-KEY* Gastric-Jejunal (GJ) enteral feeding tubes (low profile), and 16Fr-22Fr, silicone, MIC* Gastric-Jejunal (GJ) enteral feeding tubes

(conventional). In each case, the GJ-1422, when used in accordance with the Instructions for Use (IFU) (i.e., Operator's Manual), effectively cleared the required occluded Tubes in accordance with the *a priori* acceptance criteria. The acceptance criteria were the same as that used for the legally marketed TC-0608 model, indicating that GJ-1422 is substantially equivalent to TC-0608 in clearing occluded Tubes.

Clearing Stem Removal Forces: In order to ensure that the different material and geometry of the Tubes indicated for GJ-1422 do not lead to unnecessarily high removal forces that might dislodge the Tube or exceed the component strength of GJ-1422, the force required to remove the Clearing Stem from an artificially created clogged Tube was measured. In each case, the GJ-1422, when used in accordance with IFU, had lower forces than the *a priori* acceptance criteria. The acceptance criteria were the same as that used for the legally marketed TC-0608 model, indicating that GJ-1422 is substantially equivalent to TC-0608.

Feeding Tube Integrity:

Feeding tube integrity was tested against the different geometry and materials used in indicated Tubes for GJ-1422. The GJ tubes were folded and placed into *ex vivo* porcine tissue model forming a small radius curved Tube (i.e., kink). Using GJ-1422 as per the IFU, a simulated clog was first cleared, then GJ-1422 was advanced until the distal end of the Clearing Stem contacted the kink. The Operator moved the Clearing Stem backward and forward while in contact with the kink for 70 minutes. After the test, the Tubes were examined under a microscope for signs of damage. No signs of scratching or marring was observed. The Tube Integrity Tests support that GJ-1422 is substantially equivalent to TC-0608.

Flow Rate:

In order to confirm that the repeated use of Coconut Oil does not lead to accumulated residue that negatively affects the patency of the Tube, AMI completed worst-case Flow Rate testing demonstrating that repeated introduction of GJ-1422 coated in Coconut Oil into a feeding tube of the smallest French size and maximal length does not negatively alter the Tube's subsequent flow rate. The Tubes that were used with Coconut Oil showed a statistically significant higher amount of water collected, demonstrating that the Coconut Oil does not lead to accumulation of residue, nor does it reduce patency of the Tube. The Flow Rate Tests support that GJ-1422 is substantially equivalent to TC-0608.

USP Monograph Testing and Toxicological Assessment:

GMP compliant USP method verification and release testing per USP 42 for a representative sample of the Coconut Oil was performed by an accredited test laboratory. Nineteen (19) of the twenty-one (21) analytes met the USP specification. At 0.7%, the fatty acid composition, carbon chain length 18:2 was below the specific of 1.0-3.0%.

Arsenic testing could not be verified and was therefore not tested as part of the release testing.

A literature review found eight (8) clinical trials exploring the effects of consuming coconut oil. For GJ-1422, in a worst-case scenario, ≤1 mL of Coconut Oil could be administered per week. In the reviewed studies, between 140 and 378 times the weekly dose of coconut oil was administered compared to the GJ-1422 worst-case scenario. In the reviewed studies, even with the higher dose regimen, no negative effects from coconut oil consumption was reported.

A risk-based assessment of the USP monograph testing and literature-based toxicological risk assessment in totality – especially considering the disparity in volumes between the clinical studies in the literature and that potentially administered through worst-case use with GJ-1422 – indicates that GJ-1422 does not present unacceptable adverse risks to the patient.

Risk-benefit analysis:

For patients experiencing a clogged GJ tube, their prescribed enteral therapy (i.e., medication, hydration, and/or nutrition) is interrupted. Utilization of GJ-1422 provides critically ill patients with an effective alternative for clearing their clogged GJ tubes compared to the traditional Tube replacement. GJ tubes are placed either endoscopically, using topical analgesics and/or sedation, or surgically, under general anesthesia. Avoiding a Tube replacement can significantly reduce unnecessary risks for patients, whom may already be exhibiting gastrointestinal comorbidities. Successful clearings would render scheduled GJ tube replacement procedures due to clogging unnecessary, thus reducing costs for both the healthcare institution and patients. And would quickly restore their enteral therapy which is critical to the patient's health outcomes.

Conclusions

Benchtop testing in artificially clogged GJ tubes demonstrate that GJ-1422 is substantially equivalent to the predicate device (TC-0608), which is currently marketed for the same intended use.

This submission claims substantial equivalence of GJ-1422 to TC-0608 based on repeated benchtop testing of Clearing Stem Removal Forces, Benchtop Efficacy, and Feeding Tube Integrity in clogged GJ Tubes. The methodology was largely identical between the two Clearing Stem types, and the differences in methodology do not affect the validity or applicability of the results. Both Clearing Stem models TC-0608 and GJ-1422 passed their respective *a priori* acceptance criteria for each test, which reflects clinically acceptable success rates. USP monograph testing and a literature-based toxicological risk assessment indicates that the use of Coconut Oil with GJ-1422 does not

present unacceptable adverse risks to the patient. A benefit risk analysis reveals that the benefits of GJ-1422 greatly outweigh the risks, which are low in severity and infrequent in occurrence. For these reasons TubeClear Clearing Stem Model GJ-1422 (GJ-1422) is substantially equivalent to the TubeClear Clearing Stem Model TC-0608 (K163092).