DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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November 30, 2016

Actuated Medical, Inc.
% Dave Yungvirt
Third Party Review Group, LLC
The Old Station House
24 Lackawanna Place
Millburn, NJ 07041

Re: K163092
Trade/Device Name: TubeClear Control Box and Clearing Stem
Regulation Number: 21 CFR 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: Class II
Product Code: KNT
Dated: November 2, 2016
Received: November 4, 2016

Dear Dave Yungvirt,

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Joyce M. Whang -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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K163092

Device Name
TubeClear Control Box and Clearing Stem

Indications for Use *(Describe)*

TubeClear Clearing Stem Model TC-1018 is indicated for use ONLY and SOLELY in clearing occlusion / clogs in Feeding and Decompression Tubes in adults that have the following Tube type and size (French and length).

• TC-1018, for Nasoenteral and Nasogastric Tubes that are size 10 - 18 Fr and have a length of 91 - 140 cm (36 - 55 in); and Gastrostomy and Jejunostomy Tubes that are size 10 - 18 Fr and have a length of 20 - 36 cm (8 - 14 in).

TubeClear Clearing Stem Model TC-0812 is indicated for use ONLY and SOLELY in clearing occlusion / clogs in Feeding and Decompression Tubes in adults that have the following Tube type, size (French and length), and material.

• TC-0812, for Nasoenteral and Nasogastric Tubes composed of Polyvinyl Chloride (PVC) and Polyurethane that are size 8 - 12 Fr and have a length of 38 - 140 cm (15 - 55 in).

TubeClear Clearing Stem Model TC-0608 is indicated for use ONLY and SOLELY in clearing occlusion / clogs in Feeding and Decompression Tubes in adults that have the following Tube type, size (French and length), and material.

• TC-0608, for Nasoenteral and Nasogastric Tubes composed of Polyvinyl Chloride (PVC) and Polyurethane that are size 6 - 8 Fr and have a length of 38 -140 cm (15 - 55 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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SECTION 5: 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: _____

5.1: Applicant Information

Date Prepared: November 30, 2016

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5.2: Device Information

Classification: KNT
Trade Name TubeClear Control Box and Clearing Stem
Common Name: In Patient Tube Clearing System
Classification Name: Tube, Gastrointestinal and Accessories, 21 C.F.R. §876.5980
Control Box Model: 101
Clearing Stem Models: TC-0608, TC-0812, and TC-1018

5.3: Predicate Device

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

510(k) Number	Trade Name	Manufacturer
K131052	TubeClear	Actuated Medical, Inc.

The Predicate Device, TubeClear, is comprised of Control Box Model 101 and Clearing Stem Models NE-1036, NE-1042, NE-1043, NE-1045, NE-1048, NE-1050, NE-1055, G-1008, G-1009, G-1010, G-1011, G-1012, and G-1014.

5.4: Device Description

The Proposed Device, the TubeClear Control Box and Clearing Stem, is comprised of Control Box Model 101 and Clearing Stem Models TC-0608, TC-0812, and TC-1018. The Control Box is reusable and the Clearing Stems are single use. The Operator manually inserts the Clearing Stem into the feeding and/or decompression tube (i.e., Tube), while the Tube remains in the Patient, and directs the Clearing Stem's progression along the inside of the Tube. The Control Box Motor via electromechanical actuation creates a linear reciprocating motion. The linear reciprocating motion is transferred to the proximal end of the Clearing Stem which contains a Wire that also reciprocates. Because the Wire is continuous throughout the Clearing Stem, the reciprocating motion is further transferred to the distal Tip of the Wire. The motion at the Wire Tip mechanically acts on the occlusion and restores Tube patency.

Three (3) new Clearing Stem Models are proposed. The additional Clearing Stem Models expand the specific indications for use.

5.5 Intended Use

The Proposed Clearing Stem Models are substantially equivalent to the Predicate Clearing Stem Models in regards to intended use and therapeutic effect. The intended use is to clear occlusions/clogs from feeding and decompression tubes (i.e., Tubes). For both the Proposed and Predicate Clearing Stem Models, the therapeutic effect is to restore Tube patency and alleviate the need for Tube replacement.

Both the Proposed and Predicate Clearing Stem Models are disposable, single use devices. The Proposed Clearing Stem Models are intended for use by Certified or Licensed Healthcare Practitioners. The Predicate Clearing Stem Models are intended for use by Licensed Healthcare Practitioners. Human Factors Validation testing results support substantial equivalence of the expanded User group.

Both the Proposed and Predicate Clearing Stem Models are intended for use at the Patient's bedside location (e.g., hospital, non-acute care facility, Patient's home). The intended use locations support substantially equivalence of the use environment.

Both the Proposed and Predicate Clearing Stem Models enter a Tube that is within the Patient, no Model makes direct contact with the Patient. Both the Proposed and Predicate Clearing Stem Models are placed in a Tube that is in the Patient's gastrointestinal (GI) system. Both the Proposed and Predicate Clearing Stem Models do not require sterile conditions for their intended purpose.

5.6 Indications for Use

5.6.1: Specific Indications for Use of the Proposed Clearing Stem Models

TubeClear Clearing Stem Model TC-1018 is indicated for use **ONLY** and **SOLELY** in clearing occlusion / clogs in Feeding and Decompression Tubes in adults that have the following Tube type and size (French and length).

- TC-1018, for Nasoenteral and Nasogastric Tubes that are size 10 - 18 Fr and have a length of 91 - 140 cm (36 - 55 in); and Gastrostomy and Jejunostomy Tubes that are size 10 - 18 Fr and have a length of 20 - 36 cm (8 - 14 in).

TubeClear Clearing Stem Model TC-0812 is indicated for use **ONLY** and **SOLELY** in clearing occlusion / clogs in Feeding and Decompression Tubes in adults that have the following Tube type, size (French and length), and material.

- TC-0812, for Nasoenteral and Nasogastric Tubes composed of Polyvinyl Chloride (PVC) and Polyurethane that are size 8 - 12 Fr and have a length of 38 - 140 cm (15 - 55 in).

TubeClear Clearing Stem Model TC-0608 is indicated for use **ONLY** and **SOLELY** in clearing occlusion / clogs in Feeding and Decompression Tubes in adults that have the following Tube type, size (French and length), and material.

- TC-0608, for Nasoenteral and Nasogastric Tubes composed of Polyvinyl Chloride (PVC) and Polyurethane that are size 6 - 8 Fr and have a length of 38 -140 cm (15 - 55 in).

5.6.2: Specific Indications for Use of the Predicate Clearing Stem Models

TubeClear is indicated for use **ONLY** and **SOLELY** in clearing occlusions / clogs in Feeding and Decompression Tubes in adult patients that have a Tube of size 10 to 18 Fr.

The Clearing Stem Models are indicated for use as follows:

NE-1036, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 91 cm (36 in).

NE-1042, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 107 cm (42 in).

NE-1043, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 109 cm (43 in).

NE-1045, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 114 cm (45 in).

NE-1048, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 122 cm (48 in).

NE-1050, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 127 cm (50 in).

NE-1055, for Nasoenteral and Nasogastric Tubes that are of size 10 - 18 Fr and have a length of 140 cm (55 in).

G-1008, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 20 cm (8 in).

G-1009, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 23 cm (9 in).

G-1010, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 25 cm (10 in).

G-1011, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 28 cm (11 in).

G-1012, for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 30 cm (12 in).

G-1014, for Gastrostomy and Jejunostomy Tubes that are of size 10- 18 Fr and have a length of 36 cm (14 in).

The specific indications for use vary from Clearing Stem Model to Clearing Stem Model; however, the differences are not critical to the intended therapeutic use of the device, which is restoring patency to the Tube and alleviating the need for Tube replacement. The differences do not affect the safety and effectiveness of the Proposed Clearing Stem Models.

5.7: Technological Characteristics

The technological characteristics of the Proposed Device are similar to the Predicate Device. Both the Proposed and Predicate Devices have the same operating principle (i.e., Operator interaction with the Device and the Clearing Stem Wire mode of actuation). Both the Proposed and Predicate Clearing Stem Models are manually inserted and advanced into the Patient's Tube. Both the Proposed and Predicate Clearing Stem Models physically interact with the occlusion material inside a Tube. Both the Proposed and Predicate Clearing Stem Models mechanically clear occlusions restoring Tube patency.

The design features of the Proposed Device are similar to the Predicate Device. Both the Proposed and Predicate Clearing Stem Models are single use. Both the Proposed and Predicate Clearing Stem Models have rounded and flexible Wire Tips. Both the Proposed and Predicate Clearing Stems have multiple Models differentiated by color. Both the Proposed and Predicate Clearing Stem Models have informative labeling. Both the Proposed and Predicate Clearing Stem

Models have a depth limiting component that determines the Working Length (i.e., the length of the Clearing Stem that can be inserted into the Tube).

The method of attachment of the depth limiting component is different between the Proposed and Predicate Devices. The Proposed Device depth limiting component (i.e., Depth Limiter) is attached to the Clearing Stem Model by the Operator. The Predicate Device depth limiting component (i.e., Collar) is attached to the Clearing Stem Model by the Manufacturer.

Performance data and Human Factors Validation testing results support substantial equivalence of the technological characteristics of the Proposed and Predicate Devices.

5.8: Non-Clinical Performance Data

As the same Control Box (i.e., Model 101) is used with the Proposed and Predicate Clearing Stem Models, testing presented in this submission focused predominantly on the Clearing Stem. Bench Testing of the Clearing Stem focused in three areas: Technical, Efficacy, and Safety. Technical testing included verification of product specifications, Wire tip flexibility, forces on Clearing Stem, distal Wire pull force, accelerated shelf life, and packaging integrity / transportation vibration. Efficacy testing included Human Factors Validation and comparison of device effectiveness. Safety testing evaluated the potential for Tube damage (i.e., Tube Heating and Integrity), Tube movement during use of TubeClear, and Operator error coupled with abnormal use.

5.8.1: Technical Testing

Verification confirmed that the Clearing Stem Models met product specifications and all acceptance criteria. Transportation vibration testing met all acceptance criteria for US highway truck. Shelf life was tested via accelerated shelf life testing and met all acceptance criteria for 12 month storage. Additional testing for longer shelf life is ongoing.

5.8.2: Efficacy Testing

Human Factors Validation testing by certified and licensed healthcare practitioners was successfully completed. Evaluation of effectiveness during

simulated use was performed for the Proposed Clearing Stem Models and compared to the effectiveness of the Predicate Clearing Stem Models.

Human Factors Validation and comparison of device effectiveness testing results support substantial equivalence of effectiveness of the Proposed and Predicate Devices.

5.8.3: Safety Testing

Safety testing for the Proposed and Predicate Clearing Stem Models included an assessment of Tube Integrity, Tube Heating, and Tube movement. Appropriate safety tests were determined using AMI's ISO 14971-compliant system's risk management activities. Effect of Clearing Stem on Tube Integrity (e.g., scratches, nicks, tears, abrasions, punctures to the inner tube surface) was found to be substantially equivalent for both Devices use of TubeClear. Tube heating was found to be negligible and substantially equivalent for both Devices during use of TubeClear. Tube movement was found to be substantially equivalent for both Devices during use of TubeClear.

A third-party organization (Intertek Group (Boxborough, MA)) tested and found conformance to general requirements for basic safety and essential performance for medical electrical equipment, application of usability engineering, and ISO 14971 risk management framework as per consensus standards IEC-60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007), IEC 60601-1-6: 2010, and IEC 62366: 2007. The third-party organization also tested and found Electromagnetic Compatibility conformance as per consensus standard IEC 60601-1-2:2001 +A1:2004.

Safety testing results support substantial equivalence of safety of the Proposed and Predicate Devices.

5.8.4 Animal Testing

Animal testing was carried out to assess the probability that the Proposed Clearing Stem Models would puncture the intestinal lining of the patient in the event that the Clearing Stem is over-inserted into the tube. Forces generated by the worst case scenario (Depth Limiter set so Working Length is longer than Tube length) coupled with abnormal use (excessive force) on porcine jejunum tissue were analyzed on a force gauge to determine a reasonable assurance of

safety. Animal Testing results support that the Proposed Clearing Stem Design is safe for its intended use in adult patient populations and substantially equivalent to the Predicate Clearing Stem Design in terms of safety if Operator Error Coupled with Abnormal Use were to occur.

5.9: Clinical Performance Data

No clinical data was collected; therefore, no clinical data is presented in this submission.

5.10: Conclusions

The scientific data demonstrates that the Proposed Clearing Stem Models are substantially equivalent to the Predicate Clearing Stem Models. The 510(k) Substantial Equivalence Decision Making Process Flow Chart was used by Actuated Medical, Inc. to determine Substantial Equivalence.