June 29, 2018

Actuated Medical, Inc.
Michael T. Britton, M.S.
Regulatory Affairs & Compliance Leader
310 Rolling Ridge Drive
Bellefonte, PA 16823

Re: K172556
Trade/Device Name: TubeClear System
Regulation Number: 21 CFR§ 876.5980
Regulation Name: Gastrointestinal Tube and Accessories
Regulatory Class: II
Product Code: KNT
Dated: May 31, 2018
Received: June 1, 2018

Dear Michael T. Britton:

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.

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,

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)*
K172556

Device Name
TubeClear System

Indications for Use *(Describe)*

TubeClear System Clearing Stem Models are indicated for use ONLY and SOLELY in clearing occlusions/clogs in Feeding and Decompression Tubes in adult patients that have the following Tube type and size (French and length):

- 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);
- 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);
- 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);
- 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); and
- G-1014: for Gastrostomy and Jejunostomy Tubes that are of size 10 - 18 Fr and have a length of 36 cm (14 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: K172556

5.1 Applicant Information

Date Prepared: June 22, 2018

Name and Address: Actuated Medical, Inc.
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Bellefonte, PA 16823
Ph: (814) 355-0003
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Contact Person: Michael T. Britton
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5.2 Device Information

Classification: 876.5980, product code KNT
Trade Name TubeClear System
Common Name: In Patient Tube Clearing System
Classification Name: Gastrointestinal tubes and accessories.

5.3 Predicate Devices

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

510(k) Number	Trade Name	Manufacturer
K163092	TubeClear System	Actuated Medical, Inc.
K131052	TubeClear System	Actuated Medical, Inc.

5.4 Device Description

The TubeClear System is comprised of a reusable Control Box and a single use Clearing Stem. The Clearing Stem is connected to the Control Box. The Operator then manually inserts the Clearing Stem into the Feeding and Decompression Tube (i.e., 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. Control Box Model 101 is used to actuate all Clearing Stem models. Sixteen (16) Clearing Stem Models are proposed to accommodate the different types, sizes, and materials of Tubes.

5.5 Intended Use

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

5.6 Indications for Use of the Proposed TubeClear System

TubeClear System Clearing Stem Models are indicated for use ONLY and SOLELY in clearing occlusions/clogs in Feeding and Decompression Tubes in adult patients that have the following Tube type and size (French and length):

• 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);

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

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

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

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

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

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

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

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

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

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

5.7 Technological Characteristics

The TubeClear System referenced in this 510(k)-submission is technologically identical to the predicate devices. Changes include modified material of the Control Box O-Ring, combining the Clearing Stem models' labeling from each predicate device into a single Instructions for Use (IFU), and expanding the user population for the NE/G models from Licensed Healthcare Practitioners to Certified and Licensed Healthcare Practitioners to be consistent with the TC models.

5.8 Performance Data

Performance testing on the material changes demonstrate substantial equivalence to the predicate devices. Performance bench testing used to support substantial equivalence was water ingress testing of the o-ring.

5.9 Conclusions

The scientific data demonstrates that the Proposed Clearing Stem Models are substantially equivalent to the Predicate Clearing Stem Models.