ACTUATEDMEDICAL
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310 Rolling Ridge Drive
Bellefonte, PA 16823
+ p (814) 355.0003
+ f (814) 355.1532
+ w ActuatedMedical.com

Certified
+ ISO 13485 & 14971
+ 9001 Compliant
+ WBF

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 CFR807.92.

510(k) Number: K131052

5.1: APPLICANT INFORMATION

Date Prepared: August 9, 2013

AUG 1 6 2013

Name and Address: Actuated Medical, Inc.
310 Rolling Ridge Drive
Bellefonte, PA 16823
Ph: 814-355-0003
Fax: 814-355-1532

Contact Person: Victoria A. Kellogg, Ph.D., CRNP, M.B.A., Esq.
Director Medical Affairs
Ph: 814-355-0003 x118
Fax: 814-355-1532
Email: Victoria.kellogg@actuatedmedical.com

5.2: DEVICE INFORMATION

Classification: KNT
Trade Name: TubeClear
Common Name: In Patient Tube Clearing System
Classification Name: Tubes, Gastrointestinal and Accessories, 21 C.F.R. §876.5980

5.3: PREDICATE DEVICE

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

510(K) Number	Trade or Proprietary Name	Manufacturer	Comment
K121571	TubeClear	Actuated Medical, Inc.	Original and Traditional 510K Cleared 6/18/12
K123659	TubeClear	Actuated Medical, Inc.	Special 510K[1] Cleared 12/20/12

The Predicate Device, TubeClear, is comprised of Control Box Model 101 and Clearing Stem Models NG-1036 and NG-1043.

5.4: DEVICE DESCRIPTION

The Proposed 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. 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) 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.

[1] Special 510K submitted to address a change to the Clearing Stem. The change was the removal of pad-printed markings from the Clearing Stem Sheath.

Thirteen (13) 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 for both the Proposed and Predicate Clearing Stems is to clear occlusions / clogs from feeding and decompression tubes (i.e., Tubes). The therapeutic effect is restoring patency to the Tube and alleviating the need for Tube replacement.

All Models of Clearing Stem are disposable, single use devices. All Models are intended for use by Licensed Healthcare Practitioners. All Models are intended for use in hospitals, in long term care facilities, and in homes (serviced by licensed healthcare practitioners). Because all Clearing Stem Models enter a Tube that is within the Patient, no Model makes direct contact with the Patient. All models of Clearing Stems are placed into a Tube that is in the Patient's gastro-intestinal (GI) system. Sterile conditions are not required for the intended purpose.

5.6: INDICATIONS FOR USE

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).

5.6.1: Specific Indications for Use of Predicate Clearing Stem Models

Clearing Stem Model NG-1036 is indicated for use in Nasogastric tubes that are of size 10 – 14 French and have a length of 91 – 108 cm (36 – 42 in).

Clearing Stem Model NG-1043 is indicated for use in Nasogastric tubes that are of size 10 – 14 French and have a length of 109 – 127 cm (43 – 50 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 technology is the same for the Proposed and Predicate Clearing Stems. The operating principle, Operator interaction with the Device, and the mode of actuation of the Clearing Stem Wire is identical (i.e., Control Box Model 101). Both the Proposed and Predicate Clearing Stems 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. The Wire inside the Sheath is linearly actuated by the Motor inside the Control Box.

The design features of the Proposed Clearing Stem Models and the Predicate Clearing Stem Models are very similar. For both the Proposed and Predicate Clearing Stem Models, the Sheath is the same material (i.e., PTFE extruded tubing) and length. Each Model has a Collar specifically positioned to limit the depth that the Clearing Stem can be inserted into the Tube. The Collar position determines the Working Length of the Clearing Stem and is specific to each Model. The main difference between the Proposed Clearing Stem Models and the Predicate Clearing Stem Models is the Wire inside the Sheath of the Clearing Stem; specifically the Wire Tip. The Proposed Clearing Stem Design incorporates a more flexible Wire Tip than the Predicate Clearing Stem Design. The Proposed Wire Tip Design is safe and effective for the expanded indications for use.

The Wire used in the Proposed Clearing Stems is 203.340 cm (80.055 in) in length; 304V stainless steel; and a Lunderquist Style Mandrel Guide Wire. It has a stiff, fixed Core and a flexible Tip. Beginning at 109.22 cm (43.000 in) from the distal end, a flat Coil Wire is wound over the core wire creating an outer diameter of 0.089 ± 0.008 cm (0.035 ± 0.003 in). Ten (10) cm (3.937 in) from the distal end, the core wire gradually tapers over a 5.000 ± 0.500 cm (1.969 ± 0.197 in) length to 0.015 ± 0.013 cm (0.006 ± 0.005 in). The distal 5.000 ± 0.500 cm (1.969 ± 0.197 in) of the core wire are a constant 0.015 ± 0.013 cm (0.006 ± 0.005 in) in diameter. The Coil Wire is brazed onto the Core wire. The distal end of the wire is rounded and smooth with a radius of .046 cm (0.018 in).

The Wire used in the Predicate Clearing Stems is 203 cm (80 in) in length; flexible twisted 1x7 strand 304V stainless steel. The Wire diameter is 0.069 ± 0.008 cm (0.027 ± 0.003 in). The ends of the Wire are fused and rounded.

5.8: NON-CLINICAL PERFORMANCE DATA

As the same Control Box (i.e., Model 101) will be used, testing focused predominantly on the Clearing Stem. Testing for the Control Box Model 101 consisted of upgrading electrical safety testing to IEC 60601-1 3rd Edition; Medical Electrical Equipment, Part 1: General requirements for basic safety and essential performance. Testing was performed by Intertek Group (Boxborough, MA) and was successfully completed in December, 2012.

Bench Testing of the Clearing Stem focused in three areas: Technical, Efficacy, and Safety. Technical testing included verification of product specifications, transportation vibration, and shelf life. Efficacy testing included usability and effectiveness. Safety testing evaluated the potential for Tube damage, Tube heating and Tube movement during use of TubeClear.

5.8.1: Technical Testing

Verification confirmed that the Clearing Stem Models met product specifications passing all acceptance criteria. Transportation vibration testing successfully passed acceptance criteria for US highway truck. Shelf life was tested via accelerated life testing and passed 24 month storage. Additional testing for longer shelf life is ongoing.

5.8.2: Efficacy Testing

Usability testing by 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. They were found to be of equivalent effectiveness.

5.8.3: Safety Testing

Safety testing in terms of Tube damage (e.g., scratches, nicks, tears, abrasions, punctures) to the inner tube surface after device operation was found to be equivalent for the Proposed and Predicate Devices. Heating during device operation was negligible and equivalent for the Proposed and Predicate Devices, thus the Devices have equivalent safety in terms of heating. Tube movement was measured and found to be of the same magnitude, thus equivalent for both

Devices. The potential for Tube damage, Tube heating and Tube movement during use of TubeClear was found to be equivalent for the Proposed and Predicate Clearing Stems.

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.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 16, 2013

Actuated Medical, Inc.
% Jeffrey Rongero
Senior Project Engineer
UL LLC
12 Laboratory Drive
Research Triangle Park, NC 27709-3995

Re: K131052
Trade/Device Name: TubeClear™
Regulation Number: 21 CFR §876.5980
Regulation Name: Tubes, Gastrointestinal and Accessories
Regulatory Class: Class II
Product Code: KNT, FPD
Dated: July 31, 2013
Received: August 1, 2013

Dear Jeffrey Rongero,

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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 yours,

Benjamin R. Fisher -S

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

4.0 Indications for Use

510(k) Number (if known): K131052

Device Name: TubeClear

Indications for Use Statement

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.

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

Prescription Use ___X__ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Benjamin R. Fisher -S
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(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K131052