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

October 4, 2017

Q Urological Corporation
Scott Epstein
Founder / CEO
93 West Street, Suite C1
Medfield, MA 02052

Re: K172289
Trade/Device Name: pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent
Regulation Number: 21 CFR§ 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: II
Product Code: FAD
Dated: September 5, 2017
Received: September 6, 2017

Dear Scott Epstein:

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,

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

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)*
K172289

Device Name
The pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent

Indications for Use *(Describe)*
The pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent is used to facilitate drainage from the kidney to the bladder and stenting of the ureter in patients not less than 2 years old. The Stent may be placed using endoscopic, percutaneous or open surgical techniques. The Stent should not be implanted for more than 30 days. This product is not intended as a permanent indwelling device.

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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008. Special 510(k) Summary

SPECIAL 510(k) NUMBER: **K172289**

SUBMITTED BY OWNER: Q Urological™ Corporation, (**new address**: 93 West St; Suite C1, Medfield MA 02052 – 508 728 1031 - OFFICIAL CONTACT: Scott M. Epstein, President

DATE OF PREPARATION: July 21, 2017 (revised September 4, 2017)

TRADE NAME AND MODEL OF DEVICE:

pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent: Models 2 and 3

COMMON AND CLASSIFICATION NAME: Ureteral Stent

REGULATORY DESIGNATION: 21 CFR 876.4620

CLASSIFICATION: Class II

PRODUCT CODE: FAD

CLASSIFICATION PANEL: Gastroenterology / Urology

PREDICATE DEVICE:

pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent [Premarket Notification 510(k): K163068]

This predicate has not been subject to a design-related recall. No historical modifications have been made since the last clearance of the device.

INTENDED USE: To allow for the passage of urine.

INDICATIONS FOR USE:

The pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent is used to facilitate drainage from the kidney to the bladder and stenting of the ureter in patients not less than 2 years old. The Stent may be placed using endoscopic, percutaneous, or open surgical techniques. The Stent should not be implanted for more than **30** days. This product is not intended as a permanent indwelling device.

DEVICE DESCRIPTION:

The pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent meets the statutory definition of 21 CFR 876.4620 as a "tube-like", implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. Ureteral stents may have finger-like protrusions or hooked ends to keep the tube in place. They are used in the treatment of ureteral injuries and ureteral obstruction.

The purpose of this Special 510(k) is to expand the product line of the pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent [510(k) K163068], to add variations in anchorage profile. The recommended usage of the pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent, to facilitate drainage from the kidney to the bladder and stenting of the ureter in patients not less than 2 years old, remains unchanged.

Particular uses and the choice of anchorage profile are left to the physician's discretion and suggestions do not appear in the labeling. The labeling will only identify the type of anchorage profile. All stents are radiopaque. All stents by Q Urological ™ Corporation are single use, sterile devices, administrated in healthcare facilities by prescription.

As with the cleared / predicate pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent, the modified stent may be placed using endoscopic, percutaneous, or open surgical techniques. The stent should not be implanted for more than 30 days. The product is not intended as a permanent indwelling device.

The proposed stents will be made of the same material as the predicate (trademark paguamedicina™), a partiality hydrolyzed polyacrylonitrile, produced in part from a proprietary manufacturing process.

The modified device incorporates a wire form which creates a pigtail configuration upon deployment. The wire is composed of metals that have been implanted in the human body in a wide variety of locations (tissue and bone), for numerous applications and are considered to be biocompatible.

The manufacturing methods, process parameters, design controls and quality assurance system (QSR – 21 CFR 820) used for all pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stents are the same as those of the cleared / predicate device; [510(k) K163068].

The stents are sterilized by E Beam radiation to a sterility assurance level of 10^{-6}.

LEGALLY MARKETED DEVICE: The Subject of this Special 510(k) is being compared for substantially equivalence to the pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent, a legally marketed device, as originally cleared in 510(k) K163068.

SUMMARY STATEMENT:

This Special Premarket Notification proposes to expand the product line of pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stents by adding additional anchorage profiles, providing the physician the ability to select the most appropriate product for the individual patient.

Clearance of the proposed modification, which creates stents with a pigtail loop, will allow for the addition of two new devices, extending the available product offering. In one configuration, the currently cleared bulbous anchorage will be used in the bladder and the proposed pigtail anchorage in the kidney (bulbous / pigtail). In a second device, both ends of the stent will utilized the proposed pigtail anchorage (pigtail / pigtail). Both products will be available in the same sizes and lengths as the unmodified product.

The labeling of the entire product line is consistent with that of the cleared / predicate device as it displays the same insertion, retrieval / removal or exchange procedure; sterility method; stability / expiration dating; and labeled Contraindications, essential Warnings and Precautions, Complications, Single Use Designation, Limitation on Reuse and Re-sterilization and Prescription Legend. The appropriate labeling components of the modified products will be revised to reflect the particular anchorage profile.

Development of the modification of the pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent was done in accordance with 21 CFR 820.30. Compliance with other aspects of the Quality Systems Regulation (21 CFR 820) was maintained as appropriate. Regardless of anchorage profile, the stents are made from the same raw material (paguamedicina™). The manufacturing methods, process parameters, design controls and quality assurance system are also the same. The stents are sterilized by E Beam radiation to a sterility assurance level of 10^{-6}.

No non-clinical or clinical performance data are included in this Special 510(k). Substantial Equivalence was established under Design Controls by validation and verification activities performed to reflect findings of individual risk analysis.

These verification and validation activities found that any differences in the values of attributes for the modified anchorage configurations do not introduce any different questions of safety and effectiveness from the predicate / cleared product [510(k) K163068].

SUBSTANTIAL EQUIVALENCE: The proposed stents have the same intended use and indication for use as the predicate / cleared, pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent.

The information included in this 510(k) demonstrates that any differences in the technological characteristics of stents with pigtail shaped anchorage do not raise different questions of safety and effectiveness from the predicate / cleared stent. Therefore, the proposed stents are as safe and effective as the predicate / cleared device and can be considered substantially equivalent to the pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stents cleared under 510(k) K163068.