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

December 22, 2016

Q Urological Corporation
Scott Epstein
President
15 Kearncy Road
Needham, MA 02492

Re: K163068
Trade/Device Name: pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent
Regulation Number: 21 CFR 876.4620
Regulation Name: Ureteral Stent
Regulatory Class: Class II
Product Code: FAD
Dated: December 9, 2016
Received: December 14, 2016

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

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Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163068

Device Name
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 endoscopes, 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Special 510(k) Summary

SPECIAL 510(k) NUMBER: K163068

SUBMITTED BY OWNER:
Q Urological Corporation
P.O. Box 793
Natick, MA 01760
781-449-0022

OFFICIAL CONTACT:
Scott M. Epstein
President

DATE OF PREPARATION: October 10, 2016

TRADE NAME AND MODEL OF DEVICE:

pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent

COMMON AND CLASSIFICATION NAME: **Ureteral Stent**

REGULATORY DESIGNATION: **21 CFR 876.4620**

CLASS **II**

PRODUCT CODE: **FAD**

CLASSIFICATION PANEL: **Gastroenterology / Urology**

PREDICATE DEVICE:

Q Urological™ Corporation pAguaMedicina™ Structural Hydrogel Pediatric Ureteral Stent

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 between the kidney and the bladder.

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 endoscopes, 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 is a "tube-like implanted device that is inserted into the ureter to provide ureteral rigidity and allow the passage of urine. The device may have finger-like protrusions or hooked ends to keep the tube in place. It is used in the treatment of ureteral injuries and ureteral obstruction" (21 CFR 876.4620).

The purpose of this Special 510(k) is to expand the product line of a 4 French ureteral stent [510(k) K082805] to add stents in sizes 5, 6, 7 and 8 French. The recommended usage of the pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent is to facilitate temporary internal urinary drainage between the bladder and kidney and stenting of the ureter, in patients of no less than 2 years of age.

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

As with the cleared / predicate 4 French device, the 5, 6, 7 and 8 French pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent may be placed endoscopically, percutaneously, or using 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 larger sized 5, 6, 7 and 8 French stents will be made of the same raw material as the 4 French stents (trademark pAguaMedicina™ (polyaguamedicina)), a partially hydrolyzed polyacrylonitrile, produced in part from a proprietary manufacturing process.

The manufacturing methods, process parameters, design controls and quality assurance system (QSR – 21 CFR 820) used for all sizes of the pAguaMedicina™ PERSISTENT™ Structural Hydrogel Ureteral Stent are the same; [510(k) K082805] the cleared / predicate device. Technological characteristics, including composition and radiopacifier of the modified (larger size) stent are also the same as those of the cleared device (the 4 French, Q Urological™ Corporation pAguaMedicina™ Structural Hydrogel Pediatric Ureteral Stent).

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 4 French, Q Urological™ Corporation pAguaMedicina™ Structural Hydrogel Pediatric Ureteral Stent, as originally cleared in 510(k) K082805, on January 20, 2010.

SUMMARY STATEMENT:

This Special Premarket Notification proposes to extend the product line of the Q Urological™ Corporation pAguaMedicina™ Structural Hydrogel Pediatric Ureteral Stent by adding additional sizes. The word "PERSISTENT" is being added to the trade name and the term "pediatric" removed.

It is proposed that 5, 6, 7 and 8 French stents be added to the currently cleared 4 French (predicate) offering in order to give the physician the ability to select the most appropriate product for the individual patient. The 6, 7 and 8 French stents will be available in a variety of longer lengths. The possible lengths for the 5 French stent will be the same as those of the currently (cleared / predicate) 4 French stent. Appropriate labeling components will be revised to reflect the particular French and length.

The labeling of the entire product line (4, 5, 6, 7 and 8 French) is consistent with that of the cleared / predicate device as it bears 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.

Development of the 5, 6, 7 and 8 French stents was done in accordance with 21 CFR 820.30. Compliance with other aspects of Quality Systems Regulation (21 CFR 820) was maintained as appropriate. All sized stents are made from the same raw material and the same radiopacifier is used. 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 larger stents were proportional to those of the cleared / predicate 4 French stent [510(k) K082805].

SUBSTANTIAL EQUIVALENCE:

The proposed stents in sizes 5, 6, 7 and 8 French have the same intended use and indication for use as the cleared / predicate 4 French ureteral stent with the exception of the removal of an upper age limit of 12. This was done because no correlation between the appropriate size stent and age has been established. Selection of the proper size stent is the responsibility of the physician.

"PERSISTENT" is being added to the name of the product line and the word "pediatric" will be removed. The cleared / predicate 4 French stent will remain in the product line