August 6, 2018

Emmy Medical, LLC.
% Christine Santagate
Director, Northeast Regional Operations
R&Q Solutions, LLC.
15 Standish Road
Norfolk, MA 02056

Re: K181346
Trade/Device Name: CystoSure® Plus Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: July 5, 2018
Received: July 9, 2018

Dear Christine Santagate:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; 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,

Glenn B. Bell -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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K181346

Device Name
CystoSure® Plus Catheter

Indications for Use *(Describe)*

The CystoSure® Plus catheter provides access and visualization for the female urinary bladder.
The single-use CystoSure® Plus catheter provides urethral urinary catheterization and postoperative bladder irrigation/ lavage with the addition of a sealed port for passage of an endoscope. It is suitable for medium- to long-term use with a maximum patient indwelling time < 30 days.

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 8.0 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter Information

Submitter's Name:	Ronald Adams
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Contact Person:	Ronald Adams
Telephone :	508-944-5166
Fax :	844-225-4600

Date Prepared: May 1, 2018

Device Trade Name:	CystoSure® Plus Catheter
Common/Usual Name:	Catheter, Retention Type, Balloon

Regulatory Information

Regulation Name:	Urological catheter and accessories
Class:	II
Product Code(s):	EZL
Regulation Number(s):	21 CFR 876.5130
Review Panel:	Gastroenterology/Urology

Predicate Device:
K142194 CystoSure Urinary Access System

Device Description & Comparison:

The CystoSure® and CystoSure® Plus catheters are intended for use in the diagnostic visualization of the female bladder with a port to allow for the insertion of an endoscope. They are made from silicone and they are used in both surgical and diagnostic procedures for draining the bladder and enabling the visualization of internal bladder surfaces.

The differences between Cystosure® Plus and the original Cystosure® catheter are tabulated in Table 1. Engineering drawings of the Predicate Cystosure® and Subject Cystosure® Plus catheters are provided in Attachment 1. The operational characteristics and performance criteria of the two devices are identical as both are flexible tubes used for drainage and bladder access in females.

The indications for use of the device are different by necessity, as reference to the catheter system and CystoSure® cystoscope have been removed. However, the intended use of the device remains unchanged.

Indications for Use:

Intended Use/Indications for Use: The CystoSure® Plus catheter provides access and visualization for the female urinary bladder.

The single-use CystoSure® Plus catheter provides urethral urinary catheterization and postoperative bladder irrigation/lavage with the addition of a sealed port for passage of an endoscope. It is suitable for medium- to long-term use with a maximum patient indwelling time < 30 days.

Table 1. Catheter Comparison

Element	Cystosure®	Cystosure® Plus	Comments
Shaft OD	18 Fr (6.0mm)	16 Fr (5.5mm)	Shaft OD reduced for ease of insertion.
Lumen ID	3.2 mm	3.1 mm	Reduction enables shaft OD decrease.
Length	180 mm	263 mm	Nursing staff request to enhance patient comfort – moves ports away from thighs.
Check valve color	Red	Orange	Colors are standardized depending on Catheter OD. All Degania 16 Fr catheters have orange check valves.
Shaft material & durometer	8204503, 65A	8202504, 70A	Increased stiffness for ease of insertion. *See material note below.
Balloon material	8202800 or 8204498 silicone	8202504 silicone	Silicone durometer increased to support shaft OD reduction. Formulation 8202504 is substantially equivalent to 8202503 shaft material of Cystosure. *See material note below.
Balloon port label	N/A	5cc only	Improved recognition of recommended volume.

Scope Port Glue	N/A	8015412	Added glue improves port attachment strength and is not patient contacting.
Sterilization	Ethylene oxide	Ethylene oxide	Identical facility, chamber and cycle.
Biocompatibility	Silicone	Silicone	Identical
Expiration Date	3 Year Shelf Life	3 Year Shelf Life	Identical
Packaging	Pouch	Pouch	Identical

*Durometer of silicone catheters is adjusted by changing the % of additional inert filler material to silicone resin. These inert filler materials do not affect the chemical formulation and therefore there is no need to repeat biocompatibility testing.

The above changes to the CystoSure Plus catheter from the predicate CystoSure Urinary Access System catheter enable the catheter to be inserted more easily and move the catheter ports away from the patient's thighs. The CystoSure Plus catheter meets all performance criteria of the predicate CystoSure catheter.

Conclusion:

The Emmy Medical CystoSure® Urinary Access System and Cystosure® Plus catheters are substantially equivalent in materials, performance and safety characteristics.