February 9, 2018

Nellie Medical, LLC
% Christine Santagate
Director, Boston Operations
R&Q Solutions
15 Standish Road
Norfolk, MA 02056

Re: K172422
Trade/Device Name: Kohli Urinary Drainage Catheter
Regulation Number: 21 CFR§ 876.5130
Regulation Name: Urological Catheter and Accessories
Regulatory Class: II
Product Code: EZL
Dated: December 20, 2017
Received: December 27, 2017

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. 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 the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

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,

Charles Viviano -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)*
K172422

Device Name
Kohli Urinary Drainage Catheter

Indications for Use *(Describe)*
The 2-Way Kohli urinary drainage catheter is intended for urological bladder drainage only with a maximum patient indwelling time of <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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510(K) SUMMARY

Submitter Information

Submitter's Name: Ron Adams

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Contact Person: Ron Adams
Telephone: 775-800-7300

Fax: 844-225-4600

Date Prepared: December 13, 2017

Trade Name: Kohli Urinary Drainage Catheter

Common/Usual Name: Urinary drainage catheter

Device Name: Catheter, retention type, balloon

Registration Number(s): 21 CFR 876.5130

Regulation Description: urological catheter and accessories

Class: II

Product Code(s): EZL

Predicate Device(s):

- ***Primary:*** K063442 Degania Silicone All Silicone Foley Catheter, 2-Way, 3-Way and with Temperature Sensor
- ***Secondary:*** K142194 Emmy Medical, LLC, Cystosure Urinary Access System

Device Description:

The Kohli Urinary Drainage Catheter is intended for drainage of the urinary bladder.

The Kohli Urinary Drainage Catheter provides a single use access catheter with two ports: One for bladder drainage, and one for balloon inflation. The catheter encompasses only one balloon size (5cc) and length and it does not include any hydrophilic or antimicrobial coating

Indications for Use:

The 2-Way Kohli Urinary Drainage Catheter is intended for urological bladder drainage only with a maximum patient indwelling time <30 days.

Substantial Equivalence

The below table demonstrates that the Kohli subject device is substantially equivalent to the predicate devices.

Table 14-2

Substantial Equivalence Comparison Chart – Kohli Urinary Drainage Catheter

Feature/ Specification	Proposed Device	Comparison	Primary Predicate	Secondary Predicate
Manufacturer	Nellie Medical	N/A	Degania Silicone, Ltd	Emmy Medical
Device Trade Name	Kohli Urinary Drainage Catheter	N/A	All Silicone Foley Catheter, 2-Way, 3 Way and with Temperature Sensor	CystoSure Urinary Access
General Description	Urological catheter	Identical	Urological catheter and accessories	Urological catheter
510(k)	N/A	N/A	K063442	K142194
Product Code	EZL	Identical	EZL	EZL
Device Class	II	Identical	II	II
Regulation Number	21 CFR 876.5130	Identical	21 CFR 876.5130	21 CFR 876.5130
Intended Use	Bladder drainage	Identical to 2-Way drainage catheters	Bladder irrigation and drainage	Bladder irrigation and drainage
Indications for Use	The 2-Way Kohli Urinary Drainage Catheter is intended for urological bladder drainage only with a maximum patient indwelling time <30 days.	Identical to 2-Way drainage catheters	All Silicone Foley Catheter intended for urological use only. Foley Catheter 2-way: for routine drainage of the urinary bladder. Foley Catheter 3-way: for drainage of the urinary bladder and bladder irrigation. Foley Catheter with Temperature Sensor: for drainage of the urinary bladder and simultaneous monitoring of temperature.	The CystoSure Access Catheter is used to provide drainage of urine and irrigation fluids for the female bladder and to provide a passageway for the CystoSure cystoscope.
Single Use	Yes	Yes	Yes	Yes
Lumen	2-way	2-way	2 and 3-way	4-way
Materials				
Shaft	Silicone*	Identical	Silicone*	Silicone*
Funnel	Silicone*	Identical	Silicone*	Silicone*

Table 14-2

Substantial Equivalence Comparison Chart – Kohli Urinary Drainage Catheter

Feature/ Specification	Proposed Device	Comparison	Primary Predicate	Secondary Predicate
Balloon	Silicone*	Identical	Silicone*	Silicone*
Balloon Adhesive	Silicone RTV*	Identical	Silicone RTV*	Silicone RTV*
Check Valve	polypropylene	Identical	Polypropylene	polypropylene
Radiopaque strip	Co-Extruded silicone & barium sulfate	Identical	Co-Extruded silicone & barium sulfate	N/A
Occlusion	Glue	Identical	Glue	Glue
Surface Modifications - Pad Printing	black ink**	Identical	black ink**	black ink**
Coatings	None	Identical	None	None
Dimensions				
Shaft	16 FR (5.3 mm)	Identical	12-22 Fr (4.0–7.3mm)	18 FR (6.0 mm)
Length	450 mm	Identical	400 to 450 mm	175 mm
Drainage Lumen (ID)	3.4 mm	Identical	2.5 to 3.7 mm	3.2 mm
Balloon Inflation Lumen (ID)	1.0 mm	Identical	0.5 - 2.0 mm	2.0 mm
Manufacturing Process				
Extrusion	Shaft formation	Identical	Shaft formation	Shaft formation
Injection Molding	Funnel forming	Identical	Funnel forming	Funnel forming
Balloon attachment	RTV glue	Identical	RTV glue	RTV glue
Manual assembly	Check valve	Identical	Check valve	Check valve
Surgical Approach	Urethral Insertion	Identical	Urethral Insertion	Urethral Insertion
Primary Material	Silicone	Identical	Silicone	Silicone
Sterile	Yes	Yes	Yes	Yes
Sterilization Method	Ethylene Oxide	Identical	Ethylene Oxide	Ethylene Oxide

Table 14-2

Substantial Equivalence Comparison Chart – Kohli Urinary Drainage Catheter

Feature/ Specification	Proposed Device	Comparison	Primary Predicate	Secondary Predicate
Biocompatibility	Materials tested per ISO 10993	Materials tested per ISO 10993	Materials tested per ISO 10993	Materials tested per ISO 10993

*Both VMQ and RTV silicones are identical to those of the predicates. Detailed VMQ silicone formulations and silicone RTV are proprietary to manufacturer.

** Proprietary formulation of the black ink was developed by Degania Silicone and is included as part of the biocompatibility testing assessments.

Non-Clinical Performance testing

The bench testing performed verifies that the performance of the subject device is substantially equivalent in terms of critical performance characteristics to the predicate device. Testing included inflation lumen leakage, catheter strength, connector and balloon security, flow rate, balloon volume maintenance/recovery and integrity, and resistance to traction.

Biocompatibility

A complete battery of biocompatibility tests was conducted on silicone catheters using the same materials and same processes as the Kohli catheter. The results of the tests demonstrate that the subject device is biocompatible.

Sterilization

The ETO sterilization process is identical to the cycle employed for both predicate devices. A parametric validation was performed on silicone catheters whose length and lumen diameter challenge far exceed those of the proposed Kohli catheter. Both the proposed device and the predicate can be sterilized using the same cycle.

Based on the performance testing, biocompatibility evaluation, and sterilization validation, the Kohli Urinary Drainage Catheter is substantially equivalent to the primary predicate device for its intended use.

Conclusion:

The Kohli Urinary Drainage Catheter is substantially equivalent in design, materials, construction, intended use, and manufacturing processes to the predicate devices. The geometric and mass properties are the same. Based on the results of the testing and the comparability to the predicate devices, we believe that the Kohli urinary drainage catheter does not present new concerns of safety or efficacy and is thus substantially equivalent to the legally marketed predicate devices