December 26, 2023

Nuwellis Inc.
Dawn Li
Principal RA Specialist
12988 Valley View Road
Eden Prairie, Minnesota 55344

Re: K233515
Trade/Device Name: Dual Lumen Extended Length Catheter (dELC), 6F, 12 cm (320101), Dual Lumen Extended Length Catheter (dELC), 6F, 16 cm (320102)
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device and Accessories
Regulatory Class: II
Product Code: NQJ, MPB
Dated: October 31, 2023
Received: November 1, 2023

Dear Dawn Li:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Maura Rooney -S

Digitally signed by Maura Rooney -S
Date: 2023.12.26 10:43:06 -05'00'

Maura Rooney
Assistant Director

DHT3A: Division of Renal,
Gastrointestinal, Obesity
and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn,
General Hospital, and Urology Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

Submission Number *(if known)*

K233515

Device Name

Dual Lumen Extended Length Catheter (dELC), 6F, 12 cm (320101);
Dual Lumen Extended Length Catheter (dELC), 6F, 16 cm (320102)

Indications for Use *(Describe)*

The Dual Lumen Extended Length Catheter (dELC) is indicated for use up to 72 hours in attaining vascular venous access for use with the Aquadex FlexFlow® and Aquadex SmartFlow® systems for ultrafiltration therapy. It is not for pediatric use.The catheter is not intended for the infusion of medications or fluids, for laboratory sampling, or other venous access needs.

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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510(k) Summary

I. SUBMITTER

Nuwellis, Inc.
12988 Valley View Road
Eden Prairie, MN 55344

Primary Contact: Mrs. Dawn Li
Phone: 612-644-9452
Email: dawn.li@nuwellis.com

Date Prepared: October 31, 2023

II. DEVICE

Name of Device: Dual Lumen Extended Length Catheter (dELC), Model# 320101&320102

Common or Usual Name: Short-term/non-implanted blood access device

Classification Name: Blood Access Device and Accessories (21 CFR 876.5540)

Regulatory Class: II

Product Code: NQJ

III. PREDICATE DEVICE

Primary Predicate Device: 6F Dual Lumen Extended Length Catheter (dELC), K031689
Secondary Predicate: 5.2F Dual Lumen Extended Length Catheter (dELC), K041791
Reference Device: medCOMP PRO-LINE® CT Pressure Injectable CVC catheter, K093309
Reference Device: ArrowG+ard Blue Advance Midline 5.5F catheter, K161313
Reference Device: 14.5F x 24cm Hemo-Flow Double Lumen Catheter Set, K994105

The primary and secondary predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The Dual Lumen Extended Length Catheter (dELC) is a 6F reverse-tapered dual lumen venous access device with stainless steel coil reinforcement. It is inserted into peripheral

venous circulation by way of a peel away introducer. The catheter is intended for short-term use with the Aquadex FlexFlow® and Aquadex SmartFlow® Systems in attaining vascular venous access for ultrafiltration treatment of patients with fluid overload. It has two models, 320101 and 320102, with identical hub designs but different effective (insertable) shaft lengths, 12 cm and 16 cm, to adapt to the patient's body size.

The catheter has a radiopaque polyurethane shaft with two equal-sized inner lumens designed in a "double D" configuration. The shaft has a reverse-tapered design to minimize resistance to flow. Its outside diameter starts at 6F on the distal end and tapers back to 7F on the proximal end. The shaft with reinforcement provides kinking resistance and ensures consistent flow. the Catheter has female ISO 80369-compliance Luer connectors to connect with the Aquadex blood tubing set for withdrawal and infusion. Each extension tube has a clamp: blue on the blood withdrawal tube and white on the blood infusion tube. The blood is drawn up through the withdrawal lumen, which is proximal to the infusion lumen. The skived offset tip is designed to minimize blood recirculation.

V. INDICATIONS FOR USE

The Dual Lumen Extended Length Catheter (dELC) is indicated for use up to 72 hours in attaining vascular venous access for use with the Aquadex FlexFlow® and Aquadex SmartFlow® systems for ultrafiltration therapy. It is not for pediatric use. The catheter is not intended for the infusion of medications or fluids, for laboratory sampling, or other venous access needs.

VI. COMPARISION OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The subject Dual Lumen Extended Length Catheter (dELC) is identical in terms of indications for use and principles of operation to the primary predicate device (6F Dual Lumen Extended Length Catheter) and the secondary device (5.2 F Dual Lumen Extended Length Catheter). The subject Dual Lumen External Length Catheter (dELC) has the similar design and is manufactured from similar materials as the predicate devices. The minor design changes do not raise new questions regarding safety and effectiveness.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Verification and Validation testing

The subject Dual Lumen Extended Length Catheter followed verification and validation activities in accordance with Design Controls as per 21 CFR Section 820.30. Bench testing was conducted in accordance with FDA guidance on Premarket Notification[510(k)] Submission for Short-Term and Long-Term Intravascular Catheters, and ISO 10555-1 to evaluate the performance of the subject device through its shelf life on:

- Dimensional Analysis
- Shaft Stiffness
- Air Leakage into hub during aspiration
- Liquid Leakage under pressure
- Peak Tensile Force
- Pressure Drop
- Gravity Flow Rate
- Priming Volume
- Kink Resistance
- Repeated Clamping on extension tubes
- Marking adhesion
- Chemical Tolerance
- Recirculation Rate
- Cyclic Fatigue
- Aquadex System Compatibility

ISO 11135 and ISO 11607-1 were followed to evaluate sterilization and packaging of the subject device.

Biocompatibility testing

The biocompatibility evaluation for the subject Dual Lumen Extended Length Catheter was conducted in accordance with the FDA Biocompatibility Guidance, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process", Guidance for Industry and Food and Drug Administration Staff, September 2020 and International Standard ISO10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process," as recognized by FDA. The battery of tests included the following:

- Cytotoxicity
- Sensitization
- Intracutaneous Irritation
- Acute Systemic Toxicity
- Subacute Systemic Toxicity
- Material Mediated Pyrogenicity
- Genotoxicity (Bacterial Reverse Mutation Assay)
- Genotoxicity (Mouse Lymphoma Assay)
- Implantation
- Hemocompatibility (ASTM Hemolysis)
- Hemocompatibility (Complement Activation)
- Hemocompatibility (Blood Platelet and Leukocyte Count)
- Hemocompatibility (PTT)
- Chemical Characterization with Toxicological Risk Assessment
- Mechanical Hemolysis
- Thrombogenicity

VIII. CONCLUSIONS

In accordance with FDA 21 CFR Section 807.92 and based on the indications for use, technological characteristics, and safety and performance testing, the subject Dual Lumen Extended Length Catheters have the same indications for use, same operating principles, and similar performance characteristics to the predicate devices. The safety and performance of the dELC devices were evaluated through rigorous verification and validation activities. The changes in design and materials do not impact the safety and effectiveness of the subject devices. The subject dELC devices are substantially equivalent to the predicate devices.