August 13, 2025

Nuwellis, Inc.
℅ Sydney Wiggins
Sr. Regulatory Affairs Specialist
Avio Medtech Consulting
2300 Myrtle Avenue
Suite 200
St Paul, MN 55114

Re: K252226
Trade/Device Name: Dual Lumen Extended Length Catheter (dELC), 6F, 12cm (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: July 16, 2025
Received: July 16, 2025

Dear Sydney Wiggins:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252226

Device Name
Dual Lumen Extended Length Catheter (dELC), 6F, 12cm (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) #:

510(k) Summary

Prepared on: 2025-07-16

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Nuwellis, Inc.
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Correspondent Contact Telephone	4794593337
Correspondent Contact	Mrs. Sydney Wiggins
Correspondent Contact Email	syd@aviomedtech.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Dual Lumen Extended Length Catheter (dELC), 6F, 12cm (320101); Dual Lumen Extended Length Catheter (dELC), 6F, 16 cm (320102)
Common Name	Blood access device and accessories
Classification Name	Catheter, Hemodialysis, Non-Implanted, Ultrafiltration, For Peripheral Use
Regulation Number	876.5540
Product Code(s)	NQJ, MPB

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K233515	Dual Lumen Extended Length Catheter (dELC), 6F, 12cm (320101); Dual Lumen Extended Length Catheter (dELC), 6F, 16 cm (320102)	NQJ

Device Description Summary

21 CFR 807.92(a)(4)

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 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 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 the coil reinforcement, designed based on the FDA cleared 5.2F dELC via K041791, provides kinking resistance and ensures consistent flow. Depth markings are provided in 0.5cm increments along the insertable length of the catheter shaft. The proximal end of the catheter shaft and clear polyurethane extension tubes are over-molded into a polyurethane hub, which has suture wings for securement to the skin.

Additionally, the catheter has female ISO 80369-compliant luer connectors to connect with the Aquadex blood tubing set for withdrawal and infusion. When the catheter is not in use, two yellow male locking caps can be placed on the female luer connectors for reducing the risk of infection. Each extension tube has a clamp: blue on the blood withdrawal tube (marked by the withdrawal ID ring) and white on the blood infusion tube (marked by the infusion ID ring). 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.

An attached MRI tag indicates the device is MR unsafe.

Intended Use/Indications for Use 21 CFR 807.92(a)(5)

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.

Indications for Use Comparison 21 CFR 807.92(a)(5)

The indications for use for the subject device and the predicate device are the same.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device has nearly identical technological characteristics to the predicate device. The only modification made to the dELC device was the change of the Female Luer Lock Connector's material from Cryolite G-20 acrylic to the TritanTM copolyester MX731 (polyester of dimethyl terephthalate, 1,4-cyclohexanedimethanol, 2,2,4,4-tetremethyl-1,3-cyclobutanediol, mold release additive) made by Eastman. The geometry of the Female Luer Lock connector component has remained identical.
The change in the Female Luer Lock Connector component material from an acrylic multipolymer to a copolyester does not raise different questions of safety and effectiveness. The new material has a similar biocompatibility profile to the predicate and an identical mechanism of action/mode of operation. The intended use, technological characteristics, and patient-contact profile remain unchanged. Risk analysis and, where applicable, verification and validation activities confirm that the change does not introduce new or increased risks. Of note, evaluation of the updated Female Luer Lock Connector was conducted using well-established methods and no new types of performance or safety testing was required beyond what was already established for the predicate device.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

Nonclinical testing of the 6F dELC device with the updated, copolyester Female Luer Lock Connector demonstrated that the modified device is substantially equivalent to the predicate device (K233515) in terms of safety and effectiveness. Safety testing established that the new Female Luer Lock Connector material did not introduce new risks related to increased adverse tissue reactions (biocompatibility), increased patient harm from EO residuals, and reduced shelf-life. Functionality testing focused mainly on the integrity of the junction of the connector to the extension tubes. Functionality testing established that the new Female Luer Lock Connector material did not impact device effectiveness. This was determined by visual inspection of the caps for damage following IPA conditioning, the absence of catheter leakage, and suitable peak tensile force of the connector/extension tube bond.