



April 9, 2026

Maduro Medical, Inc.  
Janice Kemp  
Director RA/QA  
983 University Ave.  
Bldg. A  
Los Gatos, California 95032

Re: K253975  
Trade/Device Name: Radical 6F Access Catheter  
Regulation Number: 21 CFR 870.1250  
Regulation Name: Percutaneous Catheter  
Regulatory Class: Class II  
Product Code: QJP, DQY  
Dated: March 13, 2026  
Received: March 13, 2026

Dear Janice Kemp:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

  
**JAIME RABEN -S**

for Naira Muradyan, Ph.D.

Assistant Director

DHT5A: Division of Neurosurgical,  
Neurointerventional, and  
Neurodiagnostic Devices

OHT5: Office of Neurological and  
Physical Medicine Devices

Office of Product Evaluation and Quality  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known)  
K253975

Device Name  
Radical 6F Access Catheter

Indications for Use (Describe)

The Radical 6F Access Catheter is indicated for the introduction of intravascular catheters into the peripheral, coronary, and neuro vasculature.

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.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
Paperwork Reduction Act (PRA) Staff  
[PRASStaff@fda.hhs.gov](mailto:PRASStaff@fda.hhs.gov)

*"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."*



**510(k) SUMMARY  
K253975**

**Manufacturer/Sponsor:** Maduro Medical, Inc.  
983 University Avenue  
Building A  
Los Gatos, California 95032  
  
Phone: (408) 600-2235

**Contact:** Janice Kemp  
QA/RA Director  
(408) 600-2235  
[janice@maduromed.com](mailto:janice@maduromed.com)

**Date Prepared:** April 07, 2026

**Device Trade Name:** Radical 6F Access Catheter

**Common/Usual Name:** Catheter, Percutaneous, Neurovasculature

**Classification:** 21 CFR 870.1250, Percutaneous Catheter

**Class:** II

**Product Code:** QJP, DQY

**Predicate Device:** Radical the Dude® 7F Guide Catheter (K231393)

**Indications for Use**

The Radical 6F Access Catheter is indicated for the introduction of intravascular catheters into the peripheral, coronary, and neuro vasculature.

**Device Description**

The Radical 6F Access Catheters are sterile, single-use intravascular catheters intended to facilitate access to target vascular regions during interventional procedures. The Radical 6F Access Catheter is offered in various working lengths, and an outer diameter (OD) size designation of 6 French (Fr). The Radical 6F Access Catheter has variable stiffness along its length, incorporating hybrid ribbon technologies to maintain stability, and vary stiffness throughout the device length. The distal region of the Radical 6F Access Catheter has a hydrophilic coating.

### **Principles of Operation**

The Radical 6F Access Catheter may be used with support catheters to assist in accessing target vasculature. During use, the male luer of the RHV is attached to the proximal luer of the Radical 6F Access Catheter to create a continuous lumen through the catheter and to the RHV ports. The female luer of the RHV is typically connected to a saline drip line while the Radical 6F Access Catheter is advanced through the vasculature. Use of the Radical 6F Access Catheter relies on standard percutaneous interventional techniques, including access site preparation, introducing the catheter portion of the device, advancing the catheter under fluoroscopy, withdrawing the catheter, and closing the access site. Intended users of the Radical 6F Access Catheter are physicians who have received appropriate training in interventional techniques. The devices are provided sterile, non-pyrogenic, and are intended for single use only.

### **Comparison of Technological Characteristics with the Predicate Device**

The predicate device is the Radical the Dude 7F Guide Catheter, K231393. The only differences being the smaller inner and outer diameters and shorter length of the subject device. The predicate and subject devices share the same intended use and basic technological characteristics as shown in Table 1. A comparison of the technological characteristics of the subject, predicate and reference devices is shown in Table 1.

Table 1: Comparison of Subject and Predicate Devices

<b>Device Attribute</b>	<b>Subject Device</b>	<b>Predicate Device</b>	<b>Reference Device</b>
Product Name	Radical 6F Access Catheter	Radical the Dude 7F Guide Catheter	Benchmark Delivery Catheter
510(k) Number	K253975	K231393	K212838
Indications for Use	The Radical 6F Access Catheter is indicated for the introduction of intravascular catheters into the peripheral, coronary, and neuro vasculature.	The Radical the Dude 7F Guide Catheter is indicated for the introduction of intravascular catheters into the peripheral, coronary, and neuro vasculature.	The Benchmark Intracranial Access System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Product Code	QJP, DQY	QJP, DQY	QJP, DQY
Regulation No.	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250
Classification	Class II	Class II	Class II
Components Supplied	Catheter, Peel-away Sheath, Rotating Hemostasis Valve (RHV)	Same	n/a
<b>Materials</b>			
Catheter Shaft Material	Urethane (Tecoflex), Pebax, Nylon	Same	Commonly used medical grade plastics & stainless steel
Inner Liner	PTFE	Same	n/a
Hub Material	Polypropylene Copolymer (Repsol HPR35CMD)	Nylon (Grilamid)	n/a
Strain Relief	Polyolefin	Same	n/a
Catheter Shaft Reinforcement	Braid: 304V Stainless Steel Coil: 304V Stainless Steel	Same	n/a
Lubricious Coating	Hydrophilic Coating	Same	n/a
Radiopaque Marker Band	Platinum/Iridium	Same	n/a
Peel-away Sheath	PTFE	Same	n/a

Device Attribute	Subject Device	Predicate Device	Reference Device
RHV	Polycarbonate, Silicone	Same	n/a
<b>Dimensions</b>			
Working Length	80, 90, 95, 100, 105, 110, 115 cm	95, 105, 115 cm	95, 105, 115 cm
Inner Diameter	0.072 inches	0.082 inches	0.070 inches minimum
Outer Diameter	Proximal: 0.085 inches Distal: 0.083 inches	Proximal: 0.098 inches Distal: 0.094 inches	0.081 – 0.083 inches
Packaging	Tyvek/ Nylon/polyethylene (PE) Pouch, PE tube, Packaging card, SBS carton	Same	Commonly used medical device packaging materials
Sterilization	Ethylene Oxide (EO) SAL 10 <sup>-6</sup>	Same	Same
Pyrogenicity	Nonpyrogenic	Same	Same
Number of Uses	Single Use	Same	Same

## Nonclinical Performance Testing

The following nonclinical performance testing was conducted to demonstrate substantial equivalence.

### Bench Testing

Table 2 lists the bench testing performed to demonstrate substantial equivalence.

Table 2: Bench Testing Summary

Test	Test Method/Applicable Standard	Result
Visual Inspection	Visual inspection completed for surface defects.	Pass
Dimensional Inspection	Critical dimensions were verified.	Pass
Simulated Use Test	Simulated use in a bench anatomical model with femoral artery and radial artery access.	Pass
PTFE Delamination	Assessed for PTFE delamination at distal tip following simulated use testing.	Pass
Tensile Testing	Tensile strength measured along entire catheter length.	Pass
Torque Strength	The distal end of the catheter was constrained from movement while the proximal end was turned until failure in a simulated anatomy model.	Pass
Kink Resistance	Resistance to kink tested at various locations along the catheter shaft using successively smaller radii to challenge the catheter.	Pass
Catheter Burst	Catheter burst tested per ISO 10555-1.	Pass
Liquid Leak Test	Liquid leak tested per ISO 10555-1.	Pass
Air Leak Test	Air leak tested per ISO 10555-1.	Pass
Corrosion	Corrosion tested per ISO 10555-1.	Pass
Tip Stiffness	Compared the tip stiffness of the Radical 6F Catheter with the reference device.	Pass
Particulate Testing	During simulated use testing in an in vitro model the particle size and count were analyzed using light obscuration method and compared to the predicate.	Pass
Coating Integrity	The integrity of the hydrophilic coating was inspected before and after simulated use testing in an in vitro model.	Pass

### Biocompatibility

The subject Radical 6F Access Catheter is categorized as a limited exposure ( $\leq 24$  hours), externally communicating device with circulating blood contact in accordance with ISO 10993-1 and FDA guidance, “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.” The subject device is constructed using materials that are commonly used in the medical device industry. The subject device uses the same materials or substantially equivalent materials and same manufacturing processes as the predicate device. The following biocompatibility endpoints were assessed to confirm biocompatibility of the subject device:

- Cytotoxicity
- Sensitization
- Intracutaneous Reactivity
- Acute Systemic Toxicity
- Material-mediated Pyrogenicity
- Direct and Indirect Hemolysis
- Complement Activation
- Thrombogenicity

### **Animal Testing**

An animal study was not deemed necessary to support the substantial equivalence of the subject device to the predicate device. Bench testing was determined sufficient to support substantial equivalence.

### **Sterilization and Shelf-Life**

The Radical 6F Access Catheter is sterilized using a validated ethylene oxide (EO) process with a sterility assurance level of  $1 \times 10^{-6}$ . The sterilization method is identical for the subject and predicate devices.

The subject device's shelf-life and packaging configuration remain identical to that of the predicate device. Therefore, no shelf life testing or packaging validation was required to demonstrate substantial equivalence between the subject and predicate devices.

### **Clinical**

The non-clinical performance testing was determined to be sufficient to support the substantial equivalence of the subject device.

### **Conclusion**

The subject Radical 6F Access Catheter has similar intended use, indications for use, principles of operation, and technological characteristics as the predicate device. The technological differences identified do not raise new questions of safety or effectiveness between the subject and predicate devices. Performance testing demonstrates that the Radical 6F Access Catheter is substantially equivalent to the predicate device.