January 14, 2025

Maduro Medical, Inc.
Janice Kemp
QA/RA Director
1731 Dell Avenue
Campbell, California 95008

Re: K243577
Trade/Device Name: Radical the Dude 8F Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: December 16, 2024
Received: December 16, 2024

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 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,

Naira Muradyan -S

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

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)*
K243577

Device Name
Radical the Dude® 8F Guide Catheter

Indications for Use *(Describe)*
The Radical the Dude 8F Guide 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.

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510(k) SUMMARY

K243577

Manufacturer/Sponsor:	Maduro Medical, Inc. 1731 Dell Avenue Campbell, California 95008 Phone: (408) 600-2235
Contact:	Janice Kemp QA/RA Director (408) 600-2235 janice@maduromed.com

Date Prepared:	January 13, 2025
Device Trade Name:	Radical the Dude® 8F Guide 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 the Dude 8F Guide Catheter is indicated for the introduction of intravascular catheters into the peripheral, coronary, and neuro vasculature.

Device Description

The Radical the Dude 8F Guide Catheter (Dude 8F Catheter) is an 8 French (Fr) guide catheter designed to aid the physician in accessing the target vasculature during interventional procedures. The Dude 8F Catheter has a usable length between 80 cm and 110 cm, and an outer diameter (OD) size designation of 8 Fr. The Dude 8F Catheter has variable stiffness along its length, incorporating hybrid ribbon technologies to maintain stability and vary stiffness along the device length. The distal portion of the Dude 8F Catheter has a hydrophilic coating. The Dude 8F Catheter is packaged with a rotating hemostasis valve (RHV) and a peel-away sheath.

Principles of Operation

The Radical the Dude 8F Guide 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 Dude 8F 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 Dude 8F Catheter is advanced through the vasculature. Use of the Dude 8F 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 for the Radical the Dude 8F Guide 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 subject and predicate devices have similar technological characteristics and the same intended use as shown in Table 1. The only differences being the larger inner and outer diameters and shorter length of the subject device. A comparison of the technological characteristics of the subject, predicate, and reference devices is shown in Table 1.

Table 1: Comparison of Subject, Predicate, and Reference Devices

Device Attribute	Subject Device	Predicate Device	Reference Device	Reference Device	Reference Device
Product Name	Radical the Dude® 8F Guide Catheter	Radical the Dude® 7F Guide Catheter	TracStar LDP Large Distal Platform	CEREBASE DA Guide Sheath	Neuron MAX System
510(k) Number	K243577	K231393	K240948	K192804	K111380
Indications for Use	The Radical the Dude 8F Guide 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 TracStar LDP Large Distal Platform is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.	The CEREBASE DA Guide Sheath is indicated for the introduction of interventional devices into the neuro vasculature.	The Neuron MAX System is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Product Code	QJP, DQY	QJP, DQY	QJP, DQY	QJP	DQY
Regulation No.	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250	21 CFR 870.1250
Classification	Class II	Class II	Class II	Class II	Class II
Components Supplied	Catheter, Peel-away Sheath, Rotating Hemostasis Valve (RHV)	Same	RHV	RHV and Dilator	Hemostasis Valve Adapter (HVA), RHV, Dilator
Materials					
Catheter Shaft Material	Urethane (Tecoflex), Pebax, Nylon	Same	Commonly used medical grade polymers and metals with hydrophilic coating	Nylon, Pebax (nylon blend), and Polyurethane Segment(s)	Commonly used medical grade polymers and metals with hydrophilic coating
Inner Liner	PTFE	Same	Commonly used medical grade polymers	PTFE	Commonly used medical grade polymers
Hub Material	Nylon (Grilamid)	Same	Unknown	Polycarbonate (yellow)	Nylon, Polyurethane
Strain Relief	Polyolefin	Same	Unknown	Unknown	Unknown
Catheter Shaft Reinforcement	Braid: 304V Stainless Steel Coil: 304V Stainless Steel	Same	Reinforced with metals and polymers	304 Stainless Steel braid	Stainless Steel Braid
Lubricious Coating	Hydrophilic Coating	Same	Same	Same	Same
Radiopaque Marker Band	Platinum/Iridium	Same	Unknown	Metal Marker Band	Same

Peel-away Sheath	PTFE	Same	N/A	N/A	N/A
RHV	Polycarbonate, Silicone	Same	Unknown	Unknown	Unknown
Dimensions					
Working Length	80, 90, 95, 100, 105, 110 cm	95, 105, 115 cm	80-105 cm	70, 80, 90, and 95 cm	80 and 90 cm
Inner Diameter	0.094 inches	0.082 inches	0.088 inches	0.090 inches	0.088 inches
Outer Diameter	Distal shaft: 0.105 inches. Distal tip OD, at marker band: 0.110 inches max. Proximal OD: 0.110 inches max.	Distal shaft: 0.094 inches. Distal tip OD, at marker band: 0.098 inches max. Proximal OD: 0.098 inches max.	Distal: 0.106 inches Proximal: 0.110 inches	8F (0.105 inches)	8F (0.112 inches max)
Packaging	Tyvek/Nylon/Polyethylene (PE) pouch, PE tube, packaging card, SBS carton	Same	PE tube, PE packaging card, pouch, shelf carton box	PET/ LDPE Tyvek pouch Polypropylene tubing, SBS mounting card, SBS carton	Tyvek/Nylon pouch, PE support tube, packaging card, SBS carton
Sterilization	Ethylene Oxide (EO)	Same	Same	Same	Same
Pyrogenicity	Nonpyrogenic	Same	Same	Same	Same
Number of Uses	Single Use	Same	Same	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 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 was 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
Hydrophilic Coating Integrity	The integrity of the hydrophilic coating was inspected before and after simulated use testing in an in vitro model.	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 reference device.	Pass
Tip Stiffness	Compared the tip stiffness of the Dude 8F Catheter with the reference device.	Pass

Biocompatibility

The subject Radical the Dude 8F Guide Catheter is categorized as a limited exposure (≤ 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 and manufacturing processes as the predicate device. Therefore, based on risk analysis, the following tests were performed to confirm biocompatibility of the subject device (Table 3).

Table 3: Biocompatibility Tests and Results

Tests	Output	Result	Conclusion
Hemocompatibility: Partial Thromboplastin Time (PTT)	The test article average clotting time was higher and was not statistically significant when compared to the negative control. The test article average clotting time was lower and was not statistically significant when compared to the vehicle control.	Pass	PTT similar to the reference device.
Thrombogenicity in Canine Model	An in vivo canine test to evaluate the thrombogenic potential of the subject device compared to a comparator device.	Pass	Thrombogenicity similar to reference device.

Animal Study
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 the Dude 8F Guide Catheter is sterilized using a validated ethylene oxide (EO) process with a sterility assurance level of $1x10^{-6}$. 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 deemed necessary to support the device and packaging shelf life.

Clinical Study
The non-clinical performance and biocompatibility testing were determined to be sufficient to support the substantial equivalence of the subject device.

Conclusion
The subject Radical the Dude 8F Guide 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 and biocompatibility testing demonstrates that the Radical the Dude 8F Guide Catheter is substantially equivalent to the predicate device.