November 30, 2023

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

Re: K231393
Trade/Device Name: Radical the Dude 7F Guide Catheter
Regulation Number: 21 CFR 870.1250
Regulation Name: Percutaneous Catheter
Regulatory Class: Class II
Product Code: QJP, DQY
Dated: November 1, 2023
Received: November 1, 2023

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.

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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K231393

Device Name
Radical the Dude 7F Guide Catheter

Indications for Use *(Describe)*
The Radical the Dude 7F 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

K231393

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: November 29, 2023

Device Trade Name: Radical the Dude® 7F Guide Catheter

Common/Usual Name: Catheter, Percutaneous, Neurovasculature

Classification: 21 CFR 870.1250, Percutaneous Catheter

Class: II

Product Code: QJP, DQY

Predicate Device: RIST Cath Radial Access Long Sheath (K191551)

Indications for Use

The Radical the Dude 7F Guide Catheter is indicated for the introduction of intravascular catheters into the peripheral, coronary, and neuro vasculature.

Device Description

The Radical the Dude 7F Guide Catheter (Dude 7F Catheter) is a 7 French (Fr) guide catheter designed to aid the physician in accessing the target vasculature during interventional procedures. The Dude 7F Catheter has a usable length between 95 cm and 115 cm, and an outer diameter (OD) size designation of 7 Fr. The Dude 7F 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 7F Catheter has a hydrophilic coating. The Dude 7F Catheter is packaged with a rotating hemostasis valve (RHV) and a peel-away sheath.

Principles of Operation

The Radical the Dude 7F 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 7F 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 7F Catheter is advanced through the vasculature. Use of the Dude 7F 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 7F 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 RIST Cath Radial Access Long Sheath cleared under K191551. The predicate and subject devices share the same intended use and basic technological characteristics as shown in Table 1.

Table 1: Comparison of Subject and Predicate Devices

Device Attribute	**Subject Device**	**Predicate Device**
Product Name	Radical the Dude 7F Guide Catheter	RIST Cath Radial Access Long Sheath
510(k) Number	K231393	K191551
Indications for Use	The Radical the Dude 7F Guide Catheter is indicated for the introduction of intravascular catheters into the peripheral, coronary, and neuro vasculature.	The RIST Cath Radial Access Long Sheath is indicated for the introduction of interventional devices into the peripheral, coronary, and neuro vasculature.
Product Code	QJP, DQY	DQY
Regulation No.	21 CFR 870.1250	21 CFR 870.1250
Classification	Class II	Class II
Components Supplied	Catheter, Peel-away Sheath, Rotating Hemostasis Valve (RHV)	Sheath, Vessel Dilator, RHV
Materials		
Catheter Shaft Material	Urethane (Tecoflex), Pebax, Nylon	Chronoflex/Polyblend (distal section) Chronoflex (PEBAX) Vestamid (proximal section)
Inner Liner	PTFE	Same
Hub Material	Nylon (Grilamid)	Polycarbonate (Makrolon)
Strain Relief	Polyolefin	Same
Catheter Shaft Reinforcement	Braid: 304V Stainless Steel Coil: 304V Stainless Steel	Stainless Steel Coil (proximal) Nitinol Wire Coil (distal)
Lubricious Coating	Hydrophilic Coating	Hydrophilic Coating
Radiopaque Marker Band	Platinum/Iridium	Same
Peel-away Sheath	PTFE	N/A
RHV	Polycarbonate, Silicone	Unknown
Dimensions		
Working Length	95, 105, 115 cm	95, 100 cm
Inner Diameter	0.082 inches	0.079 inches
Outer Diameter	Distal shaft: 0.094 inches Distal Tip OD, at marker band: 0.098 inches max. Proximal OD: 0.098 inches max.	0.093 inches

Device Attribute	Subject Device	Predicate Device
Product Name	Radical the Dude 7F Guide Catheter	RIST Cath Radial Access Long Sheath
Packaging	Tyvek/ Nylon/polyethylene (PE) Pouch, PE tube, Packaging card, SBS carton	Same
Sterilization	Ethylene Oxide (EO)	Same
Pyrogenicity	Nonpyrogenic	Same
Number of Uses	Single Use	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

Tests	Test Method/Applicable Standard	Result
Visual Inspection	Visual inspection completed for surface defects.	Pass
Dimensional Verification	Critical dimensions were verified.	Pass
Simulated Use Test (via radial artery)	Simulated use in a bench anatomical model with radial artery access.	Pass
Simulated Use Test (via femoral artery)	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 Strength	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
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 predicate.	Pass
Tip Stiffness	Compared the tip stiffness of the Dude 7F Catheter with the predicate device.	Pass
Radiopacity	Radiopacity of the device was evaluated in an animal model under fluoroscopy.	Pass

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.

Biocompatibility

The subject Radical the Dude 7F 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.

All patient contacting components of the subject device have been evaluated for biocompatibility using the following tests (Table 3).

Table 3: Biocompatibility Tests and Results

Tests	**Results**	**Result**	**Conclusion**
Cytotoxicity MEM Elution (ISO 10993-5)	Grade=0 (Reactivity None)	Pass	Non-cytotoxic
Sensitization Magnusson-Kligman Method (ISO 10993-10)	Normal saline (NS) Extract: Grade = 0 Sesame oil (SO) Extract: Grade = 0	Pass	Non-sensitizing
Irritation Intracutaneous Reactivity (ISO 10993-10)	NS Extract Difference = 0.0 SO Extract Diff. = 0.1	Pass	Non-irritant
Acute Systemic Toxicity Injection (ISO 10993-11)	No evidence of systemic toxicity from sample extracts (both NS and SO extracts): • No deaths • No signs consistent with toxicity • No weight loss > 10%	Pass	Non-toxic
Material-Mediated Pyrogenicity (USP <151>)	No single animal showed a temperature rise of 0.5°C or more above its baseline temperature.	Pass	Non-pyrogenic
Hemocompatibility:			
Hemocompatibility: Hemolysis Direct and Indirect (ISO 10993-4)	Direct Contact: Hemolytic Index = -0.2% Indirect Contact: Hemolytic Index = 0.6%	Pass	Non-hemolytic

Tests	Results	Result	Conclusion
Hemocompatibility: Complement Activation (ISO 10993-4)	The SC5b-9 concentration of the test article sample was lower than the activated normal human serum (NHS) and was similar to the negative control.	Pass	Non-activator of complement system
Hemocompatibility: Partial Thromboplastin Time (PTT)	The plasma exposed to the test article had a final average clotting time that was 90% of the negative control.	Acceptable	No effect on the PTT
Thrombogenicity in Canine model	An in vivo canine test to evaluate the thrombogenic potential of the subject device compared to a comparator device.	Pass	Non-thrombogenic
Platelet and Leukocyte Count	Average platelet count is 82.2% of the negative control. Average leukocyte count is 83.5% of the negative control.	Pass	Subject device counts are within acceptable ranges and are similar to the control.

Per the completed biocompatibility testing, the requirements and performance specifications for the subject device were met, as the device was shown to be non-cytotoxic, non-sensitizing, non-irritant, non-toxic, non-pyrogenic, non-hemolytic, and non-thrombogenic.

Sterilization

The subject Radical the Dude 7F Guide Catheter will be sterilized using a validated EO process with a sterility assurance level (SAL) of 10^{-6}. The validation will be conducted using the overkill method according to ISO 14937:2009 "Sterilization of health care products – General requirements for characterization of a sterilizing agent and the development, validation and routine control of a sterilization process for medical devices."

Shelf Life and Packaging

Accelerated aging testing based on ASTM F1980 was conducted to verify packaged device performance. Accelerated aging equivalent to 1-year of real time shelf life was used to support the 1-year shelf-life claim. Device performance was verified by functional and performance testing.

Clinical Testing

A clinical study was not deemed necessary for this submission. Substantial equivalence of the subject device to the predicate has been established through the results of nonclinical testing.

Conclusion

The subject Radical the Dude 7F 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 testing demonstrates that the Radical the Dude 7F Guide Catheter is substantially equivalent to the predicate device.