May 6, 2020

MEDRON, LLC
David Kujawa
QARA Manager
1518 S Gladiola Street
Salt Lake City, UT 84104

Re: K192283
Trade/Device Name: MEDRON Vessel Dilator
Regulation Number: 21 CFR 870.1310
Regulation Name: Vessel Dilator For Percutaneous Catheterization
Regulatory Class: Class II
Product Code: DRE
Dated: April 1, 2020
Received: April 2, 2020

Dear David Kujawa:

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 (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 located 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.

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 803) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

for

Misti Malone
Assistant Director
DHT2C: Division of Coronary
and Peripheral Intervention Devices
OHT2: Office of Cardiovascular 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192283

Device Name
MEDRON Vessel Dilator

Indications for Use *(Describe)*
The MEDRON Vessel Dilator is designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein or artery.

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.

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510(k) Summary

510(k) Sponsor: MEDRON, LLC
1518 S Gladiola Street
Salt Lake City, UT 84104

Contact Person: David Kujawa
Manager, QARA
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Date Prepared: March 31, 2020

Prepared by: Ryan O'Callaghan, MS, RAC
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Trade Name: MEDRON Vessel Dilator
Common Name: Vessel dilator
Classification Name: Vessel dilator for percutaneous catheterization (21 CFR 870.1310)
Product Code: DRE
Predicate Device: Medcomp Vessel Dilator (K162389)

1. Device Description

The MEDRON Vessel Dilator is a dilator consisting of a radiopaque HDPE (high density polyethylene) shaft with an overmolded HDPE Hub. The dilator comes in a variety of diameters ranging from 6F to 17.5F. It is also available in two models, a straight model and a stepped model. The straight model has a consistent diameter along the length of the shaft until it tapers at the distal tip. In the stepped model, the distal segment of the dilator shaft has a smaller diameter than the proximal segment as well as a taper at the distal tip.

2. Intended Use

The MEDRON Vessel Dilator is intended for short-term vascular access for percutaneous catheterization.

The intended use of the subject device is identical to the intended use of the predicate device.

3. Indications for Use

The MEDRON Vessel Dilator is designed for percutaneous entry into a vessel in order to enlarge the opening of the vessel for the placement of a catheter in a vein or artery. The subject device and predicate device have identical indications for use statements.

4. Technological Characteristics

As shown in the table below, the technological characteristics of the subject device, the MEDRON Vessel Dilator, are substantially equivalent to those of the predicate device, the Medcomp Vessel Dilator.

Comparison between Subject & Predicate Device Technological Characteristics			
Characteristic	**Predicate Device** **Medcomp Vessel Dilator (K162389)**	**Subject Device** **MEDRON Vessel Dilator**	**Comparison**
Dimensions	***O.D.:*** 4F to 24F ***Length:*** 6”, 8” ***Guidewire Sizes:*** 0.025”, 0.035”, 0.038”	***O.D.:*** 6F – 17.5F ***Length:*** 8.40 in – 8.66 in ***Guidewire Sizes:*** 0.018”, 0.038”	Equivalent
Materials: Dilator Body	High Density Polyethylene	High Density Polyethylene	Same
Materials: Dilator Hub	High Density Polyethylene	High Density Polyethylene	Same

Comparison between Subject & Predicate Device Technological Characteristics			
Characteristic	**Predicate Device** **Medcomp Vessel Dilator (K162389)**	**Subject Device** **MEDRON Vessel Dilator**	**Comparison**
Sterilization Method	EO	EO	Same

Results of tests performed on the subject demonstrate that it meets the requirements of relevant standards. Further, any differences in technological characteristics of the MEDRON Vessel Dilator when compared with predicate device characteristics do not raise different questions of safety and effectiveness.

5. Non-Clinical Performance Tests

Biocompatibility

Biocompatibility of the MEDRON Vessel Dilator has been verified in accordance with ISO 10993-1:2009 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process* and FDA's Guidance for Industry and Food and Drug Administration Staff *Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"* issued June 16, 2016.

The results of the following biological and toxicological safety evaluations verified the biocompatibility of the subject device when tested as an external communicating, blood contact, limited duration (≤24 hours) device:

- Cytotoxicity;
- Sensitization;
- Irritation/Intracutaneous Reactivity;
- Acute Systemic Toxicity;
- Materials-Mediated Pyrogenicity;
- Hemocompatibility (Hemolysis by Direct Contact and Extract); and
- Complement Activation (SC5b-9).

Results of these tests are summarized in the following table.

Summaries of Biocompatibility Tests Conducted to Support this Premarket Notification		
Test	**Results**	**Conclusions**
Cytotoxicity [L-929 MEM Elution]	Cell culture treated with test sample exhibited no reactivity (Grade 0).	Non-cytotoxic
Sensitization [Maximization (Magnusson-Kligman)]	Challenge sites treated with test sample exhibited no erythema or edema (Grade 0).	Negative for dermal sensitization
Irritation [Intracutaneous Toxicity (ISO)]	The mean test score in 0.9% Normal Saline extract was 0, and in Sesame Oil was 0.5.	Non-irritating
Systemic Toxicity (Acute) [Systemic Injection (ISO)]	No study animals were observed with abnormal clinical signs indicative of toxicity during the 72-hour test period.	Non-toxic
Systemic Toxicity (Acute) [Material Mediated Pyrogen in a Rabbit Model]	Temperature increases for the all test animals did not exceed the acceptable test limit for maximum individual temperature rise.	Non-pyrogenic
Hemocompatibility [Hemolysis, direct contact - device/material (human blood)]	The difference between the hemolytic indices of the test article and the negative control was 0.00%.	Non-hemolytic

Summaries of Biocompatibility Tests Conducted to Support this Premarket Notification		
Test	**Results**	**Conclusions**
Hemocompatibility [Hemolysis, Extract – device/material (human blood)]	The difference between the hemolytic indices of the test article and the negative control was 0.08%.	Non-hemolytic
Complement Activation [SC5b-9]	The activation caused by the test article was similar to the activation caused by the negative control after 30 and 60 minutes exposure and lower than the activation caused by the negative control after 90 minutes exposure.	Negative for complement system activation

Functional Testing

The following table summarizes the functional tests performed on unaged (t=0) and 1-year real time aged samples and results obtained to demonstrate substantial equivalence to the predicate device.

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Dimensional Verification	Dimensional inspection per engineering drawings	All devices met dimensional specifications.
Hub Workmanship	Visual inspection of hub for French size identification as well as extraneous matter and process or surface defects	All devices met acceptance criteria for size identification and were free of extraneous matter and process or surface defects

Summaries of Functional Tests Conducted to Support this Premarket Notification		
Test	**Test Method Summary**	**Results**
Luer Taper	Inspection for luer taper in accordance with ANSI/HIMA MD70.1-1983 and ISO 594-2	All samples met the criteria specified in ANSI/HIMA MD70.1-1983 and ISO 594-2
Tensile Strength	Tensile testing at hub and shaft joint per ISO 11070	All devices met minimum force breakage requirements specified in ISO 11070.
Tip Workmanship	Visual inspection of dilator tips deformation, discoloration or process or surface defects	All device tips were free of deformation, discoloration and process or surface defects
Guidewire Test	Compatibility with standard guidewires evaluated by passing guidewire through the dilator from hub end to tip	All devices met acceptance criteria as the guidewire passed through the dilators from hub to tip without drag

6. Conclusion

MEDRON, LLC has presented information in this premarket notification supporting its contention that the MEDRON Vessel Dilator is substantially equivalent with respect to technological characteristics and indications for use to the predicate device.