June 23, 2023

Saudi Mais Co. for Medical Products
% Vaibhav Rajal
Official Correspondent for Saudi Mais Co. for Medical Products
mdi Consultants Inc
55 Northern Blvd, Suite 200
Great Neck, New York 11021

Re: K221827
Trade/Device Name: Mais Central Venous Catheter
Regulation Number: 21 CFR 880.5200
Regulation Name: Intravascular Catheter
Regulatory Class: Class II
Product Code: FOZ
Dated: May 24, 2023
Received: May 24, 2023

Dear Vaibhav Rajal:

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,

Porsche Bennett

For David Wolloscheck, Ph.D.
Assistant Director
DHT3C: Division of Drug Delivery and
General Hospital Devices,
and Human Factors
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K221827

Device Name
Mais Central Venous Catheter

Indications for Use *(Describe)*
Mais central venous catheters are indicated to provide short-term access (<30 days) to the central venous system.

They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and central venous pressure monitoring.

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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K221827- 510(k) SUMMARY

Date Summary Prepared: June 23, 2023

1. Submitter's Identification:

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email: vaibhav@mdiconsultants.com

3. Subject Device:

Trade/Device Name:	Mais Central Venous Catheter
Common Name:	Short-Term Less Than 30 Days Therapeutic Intravascular Catheter
Regulation Description:	Intravascular catheter
Regulation Number:	21 CFR 880.5200
Regulatory Classification:	Class II
Product Code:	FOZ

4. Predicate Device

510(k) Number:	K190855
Trade/Device Name:	BD Acute Central Line
Regulation Number:	21 CFR 880.5200
Regulation Name:	Intravascular catheter
Regulatory Classification:	Class II
Product Code:	FOZ

5. Indications for Use Statement:

Mais central venous catheters are indicated to provide short-term access (<30 days) to the central venous system.

They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and central venous pressure monitoring.

6. Device Description:

Mais Central Venous Catheter is a radio opaque catheter, which is placed mainly in the subclavian, or jugular veins down to the right auricle as a short-term channeling access to the central venous system for central administration of drugs and central infusion of fluids and transfusion of blood.
The device provides pre-operative access to infuse anesthesia drugs and quick central access in emergencies as cardiac standstill, shock, etc.
Measuring the central venous pressure can be achieved by connecting the central lumen to the measuring device tube.

Central venous (CV) catheters can be used in anesthesia, critical care, and emergency medicine.

The correct positioning of the central venous catheter is of key significance for therapeutic success.

For most applications, placement in the superior vena cava approximately 2cm before the opening into the right atrium is viewed as the optimal position for the catheter tip.

The CV Catheter is needle punctured and surgically inserted into the superior vena cava (a large vein) of a patient. It can be planted inside for one-month maximum.

Positions for the insertion:

For Mais Central Venous Catheter, there are three optional puncture points depended on the clinical requirement with Seldinger Technique. They respectively are:

- Internal jugular vein; or
- Subclavian vein; or
- Femoral vein

The Seldinger Technique itself has the specific requirements and procedures to perform this treatment. Therefore, the device must be strictly used by trained, qualified doctors or nurses only.

Catheter's Technical Description:

Mais Catheters are made from soft polyurethane material and have double, triple or quadruple lumens, and the length is variable. The Mais catheter consists of a white radio opaque multi lumen tube which is tipped with a soft polyurethane material and has many side holes relevant to each lumen. There are markings along the effective length to indicate each centimeter. There is a connector which connects the catheter lumen(s) to a lumen of a transparent polyurethane extension tube so each catheter lumen is connected to a specific extension line. The connector is polyurethane and nearly triangular shaped. Each extension tube is marked to indicate which catheter lumen is attached to it. Distal lumen is used for the CVP monitoring. A flat clamp is put over each extension tube. The flat clamp is colored differently for a given multi lumen catheter.

The Mais Central Venous Catheter is available in different sizes as shown below:

#	Product Code	Catheter Description	Flow Rate (ml/min)		Priming Volume (ml/min)	
			Distal Lumen	Medial Lumen	Distal	Medial
1	623-0405	Double-lumen4F-5cm	19	22	0.16	0.17
2	623-0460	Double-lumen4F-6cm	15	18	0.16	0.18
3	623-0408	Double-lumen4F-8cm	16	16	0.16	0.172
4	623-0413	Double-lumen4F-13cm	13	13	0.192	0.2
5	623-0560	Double-lumen5F-6cm	34	32	0.2	0.16
6	623-0508	Double-lumen5F-8cm	29	32	0.2	0.17
7	623-0515	Double-lumen5F-15cm	23	22	0.21	0.23
8	623-5508	Double-lumen5.5F-8cm	25	23	0.3	0.33
9	623-5513	Double lumen 5.5F-13cm	26	24	0.32	0.331
10	623-0715	Double-lumen7F-15cm	93	40	0.45	0.43
11	623-0720	Double-lumen7F-20cm	77	35	0.46	0.42
12	623-0730	Double-lumen7F-30cm	68	28	0.62	0.53

#	Product Code	Catheter Description	Flow Rate (ml/min)			Priming Volume (mL/min		
			Distal	Medial	Prox.	Distal	Medial	Prox.
13	625-0515	Triple lumen 5F-15cm	32	20	22	0.17	0.39	0.35
14	625-5505	Triple-lumen5.5F-5cm	39	22	23	0.18	0.145	0.18
15	625-5506	Triple lumen 5.5F-6cm	37	21	22	0.19	0.149	0.182
16	625-5508	Triple-lumen5.5F-8cm	35	18	19	0.201	0.156	0.18
17	625-5513	Triple-lumen5.5F-13cm	29	12	12	0.23	0.23	0.2
18	625-0715	Triple-lumen7F-15cm	63	25	26	0.372	0.3	0.314
19	625-0720	Triple-lumen7F-20cm	54	20	20	0.437	0.332	0.345
20	625-0730	Triple-lumen7F-30cm	46	15	16	0.52	0.37	0.402
21	625-7520	Triple lumen 7.5F-20cm	55	22	21	0.65	0.44	0.36
22	625-0820	Triple lumen 8F-20cm	57	24	23	0.71	0.48	0.39

#	Product Code	Catheter Description	Flow Rate (ml/min)				Priming Volume (ml/min)			
			Distal	Med. 1	Med. 2	Prox.	Distal	Med. 1	Med. 2	Prox.
23	627-7520	Quad-lumen7.5F-20cm	45	52	35	34	0.49	0.41	0.31	0.34

There are variants available in central venous catheter; double lumen, triple lumen and quad lumen catheters which have various sizes and lengths.

7. Comparison to the 510(k) Cleared Device (Predicate Device):

<table>
<tr><th>Attributes</th><th>Proposed Subject Device</th><th>Predicate Device:
Bard Incorporated K190855</th><th>Discussion</th></tr>
<tr><td>Indications for Use</td><td>Mais central venous catheters are indicated to provide short-term access (<30 days) to the central venous system.

They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal and central venous pressure monitoring.</td><td>Acute central venous catheters are indicated to provide short-term access (<30 days) to the central venous system.

They are designed for administering I.V. fluids, blood products, drugs and parenteral nutrition solutions, as well as blood withdrawal, central venous pressure monitoring, and power injection of contrast media.
<table>
<tr><th>Catheter Length</th><th>Lumen</th><th>Power Injection Flow Rate</th><th>Maximum Power Injection Pressure Setting</th></tr>
<tr><td rowspan="2">16 cm and 20 cm</td><td>Distal</td><td>10mL/sec</td><td rowspan="4">325 psi</td></tr>
<tr><td>Medial/ Proximal</td><td>9ml/sec</td></tr>
<tr><td rowspan="2">30 cm</td><td>Distal</td><td>9mL/sec</td></tr>
<tr><td>Medial/ Proximal</td><td>7mL/sec</td></tr>
</table></td><td>Different
Please see comment# 1</td></tr>
<tr><td>Intended Use</td><td>Mais Central Venous Catheter System is intended for short-term access to the central venous system for intravenous therapy and blood sampling.</td><td>BD Acute Central Lines are intended for short-term access to the central venous system for intravenous therapy and blood sampling.</td><td>Same</td></tr>
<tr><td>Length</td><td>5cm, 6 cm, 8 cm, 10cm, 13 cm, 15 cm, 20 cm, 30 cm</td><td>16 cm, 20 cm and 30 cm</td><td>Different
Please see comment# 2</td></tr>
<tr><td>Device Description</td><td>Mais central venous catheters constructed of medical grade polyurethane, is designed for insertion into the central venous line with Radiaopaque, and have a soft tip that is more pliable than the catheter body. Each catheter is provided in a sterile package.</td><td>A family of central venous catheters constructed of medical grade polyurethane and is designed for insertion into the central venous catheter with radiopaque, and have a soft tip that is more pliable than the catheter body. Each catheter is provided in a sterile package.</td><td>Same</td></tr>
<tr><td>Catheter Dimension</td><td>Double-lumen4F-5cm
Double-lumen4F-6cm
Double-lumen4F-8cm
Double-lumen4F-13cm
Double-lumen5F-6cm
Double-lumen5F-8cm
Double-lumen5F-15cm
Double-lumen5.5F-8cm
Double lumen 5.5F-13cm
Double-lumen7F-15cm
Double-lumen7F-20cm
Double-lumen7F-30cm
Triple lumen 5F-15cm
Triple-lumen5.5F-5cm
Triple lumen 5.5F-6cm
Triple-lumen5.5F-8cm
Triple-lumen5.5F-13cm
Triple-lumen7F-15cm
Triple-lumen7F-20cm
Triple-lumen7F-30cm
Triple lumen 7.5F-20cm
Triple lumen 8F-20cm
Quad-lumen7.5F-20cm</td><td>7 Fr Triple Lumen x 16 cm
7 Fr Triple Lumen x 20 cm
7 Fr Triple Lumen x 30 cm</td><td>Different
Please see comment# 3</td></tr>
<tr><td>Primary Device Materials</td><td>Catheter Base Materials

Shaft Tubing- Polyurethane

Luer Connector- Polyurethane</td><td>Catheter Base Materials

Shaft Tubing- Polyurethane

Luer Connector- Polyurethane

Extension Legs- Polyurethane</td><td>Same</td></tr>
</table>

	Extension Legs- Polyurethane Junction- Polyurethane	Junction- Polyurethane	
Duration of Use	Short term (<30 days)	Short term (<30 days)	Same
Means of insertion	Percutaneous	Percutaneous	Same
Insertion Site (Anatomical site - route)	Jugular, subclavian, or femoral veins	Jugular, subclavian, or femoral veins	Same
No. of Lumens	Double Lumen, Triple Lumen, Four Lumen	Triple Lumen	Different Please see comment# 4
Catheter Proximal Configuration	Side-hole skive	Side-hole skive	Same
Catheter Distal Configuration	Formed Tip	Formed Tip	Same
Sterilization Method	Ethylene Oxide	Ethylene Oxide	Same
Sterility Assurance Limit (SAL)	The SAL is 10^{-6} Utilizing the existing validated and revalidation cycle	10^{-6}	Same
EO residuals	0.006ppm	Unknown	Unknown, Please see comment #5
Catheter Body material	Polyurethane (Medical Grade)	Polyurethane (Medical Grade)	Same
Package	Sterile package.	Sterile package.	Same

Discussions of differences in technological characteristics:

Comment# 1. The basic indications for use statement of the subject device and the predicate device are identical except that the predicate device has an additional feature of power injection of contrast media which is not a part of the subject device. The absence of this feature does not raise new concerns of safety or effectiveness in the subject device presentation.

Comment # 2. The additional catheter lengths are provided for the different age groups of patients and the site of application of the catheter. Based on performance testing conducted such as mechanical testing to ISO 10555-1, 10555-3, Flow Rate by Gravity Testing, Breaking load testing, and Anti obstructive ml/min test, it was established that the additional catheter lengths of 6, 8, 10, 13, 15 and 25 cm do not raise different questions of safety or effectiveness.

Comment # 3. Based on performance testing conducted such as mechanical testing to ISO 10555-1, 10555-3, Flow Rate by Gravity Testing, Breaking load testing, and Anti obstructive ml/min test, it was established that the additional catheter dimensions for the subject device do not raise questions of safety or effectiveness.

Comment # 4. The subject device Mais central venous catheter is available as a double lumen, triple lumen, and quadruple lumen whereas the predicate device is available as triple lumen. Based on performance testing conducted such as mechanical testing to ISO 10555-1, 10555-3, Flow Rate by Gravity Testing, Breaking load testing, and Anti obstructive ml/min test to ISO 10555, ISO 11135 standards demonstrate adequate performance with double, triple, and quadruple lumens and therefore do not raise different questions of safety and effectiveness.

Comment # 5. The EO residuals for the predicate device are unknown; however, the subject device has been tested to ISO 11135:2014 and the residuals are acceptable and therefore, the potential differences do not raise new or different questions to safety and effectiveness.

8. Performance Testing

A. The Mais Central Venous Catheter described in this summary was tested and demonstrated to be in conformance with the following FDA recognized standards:

- ISO 10555-1 2013, Intravascular Catheters - Sterile and Single-Use Intravascular Catheters - Part 1: General Requirements [Including AMENDMENT 1 (2017)]
- ISO 10555-3 2013 Intravascular Catheters – Sterile and Single-Use Intravascular Catheters- Part3: Central Venous Catheters
- Leak Test - Test to confirm that the catheter assembly will not leak when the distal end of the catheter is occluded.
- The identity of the length/Dimension Test -Test to measure useful length for catheters to ensure compliance with dimensional specification.
- The identification of extension tube/ Extension leg length test - Test to measure and confirm extension leg length compliance with dimensional specification.
- Flow rate by gravity - Test to measure the gravity flow performance of a full-length catheter.
- Breaking Load (Tensile Force) - Test to demonstrate the peak tensile force of each test piece exceeds the minimum peak tensile force. Result: All the below mentioned parts of the device are within the acceptable range i.e. Force required ≥ 15N as per ISO 10555-1:2013
    - Tube body
    - Tube and hub
    - Branch tube and hub
    - Branch tube body
    - Tip
- Anti-obstructive ml/min - Test to estimate anti obstructive ml/min at the proximal and distal part of the catheter
- Coordination of slipping buckle (Clamp Engagement) - Test to confirm that the catheter assembly will not leak when the clamp is engaged.
- Radiopacity - Test to demonstrate catheter radio-detectability
- Luer Testing - Testing to ensure that luer connectors meet requirements for
    - Leak
    - Leak Decay
    - Stress Cracking
    - Resistance to Separation from Axial Load
    - Resistance to Separation from Unscrewing
    - Resistance to Overriding
    - Gauging as per ISO 80369-7:2017

- Particulate Testing/ Particle pollution Testing to ensure that particulate matter on the catheter post-manufacture is not exceeded for prescribed particle sizes. Reference Standard: USP: Sizing and Counting Particulate Matter

The subject device was tested as per the requirements of 10555-3 test standard. The subject device is in compliance with the requirements of 10555-3 test standard and does not raise issues of safety or effectiveness.

B. Biocompatibility

In accordance with ISO 10993-1 the Central Venous Catheter is classified as: Externally Communicating Device, Blood Path (Circulating blood), Prolonged Contact (>24hr to 30days). The following testing was conducted:

- Cytotoxicity

- Sensitization
- Irritation/Intracutaneous
- Acute Systemic Toxicity
- Subchronic Toxicity
- Bacterial Reverse mutation assay
- Hemolysis
- Implantation

Particulate matter testing was conducted in accordance with USP <788> Particulate Matter in Injections and met the USP acceptance criteria.

9. Sterilization and Stability Information

The subject device complies with sterilization requirements of ISO 11135:2014, Sterilization of Health Care Products –Ethylene Oxide – Part 1: Requirements for Development, Validation and Routine Control of a Sterilization Process for Medical Devices.

- Package integrity: We evaluated the device for simulated shipping by testing for all its applicable performance and package testing in compliance with ISO 11607, ASTM F1886, ASTM F1929 and ASTM F88 standards after passing through different transportation medium and found to be free from any kind of change in physical, chemical, microbiological and the package status of the device.
    - ISO 11607-1:2006 +A1:2014 - Packaging For Terminally Sterilized Medical Devices - Part 1: Requirements For Materials, Sterile Barrier Systems And Packaging Systems [Including: Amendment 1 (2014)]

- The subject device, Mais Central Venous Catheter is provided in a sterile package. The proposed subject device, Mais Central Venous Catheter is in compliance with the following standards:
    - Visual Inspection – ASTM F1886
    - Dye Migration Test – ASTM F1929
    - Seal Peel Test - ASTM F88/EN868-5
    - 11135 Second Edition 2014-07-15 - Sterilization Of Health-Care Products - Ethylene Oxide - Requirements For The Development, Validation And Routine Control Of A Sterilization Process For Medical Devices [Including: Amendment 1 (2018)]
    - 11737-1 Third Edition 2018-01 - Sterilization Of Health Care Products - Microbiological Methods - Part 1: Determination Of A Population Of Microorganisms On Product
    - 11737-2 Second Edition 2009-11-15 - Sterilization Of Medical Devices - Microbiological Methods - Part 2: Tests Of Sterility Performed In The Definition, Validation And Maintenance Of A Sterilization Process

- The Shelf Life of 4 years based on the validation documentation of real aging from Study start date of 09-14-2014 to Study Completion date of 07-30-2018.

Conclusions:

The differences between the Mais Central Venous Catheter and the predicate device do not raise any new or different questions of safety or effectiveness. The subject device, Mais Central Venous Catheter is substantially equivalent to the predicate device, BD Acute Central Line, cleared under K190855.