September 22, 2025

JMS North America Corporation
Sho Hosoki
Director QA/RA
22320 Foothill Blvd. Suite 350
Hayward, California 94541

Re: K251877
Trade/Device Name: JMS CAVEO A.V. Fistula Needle Set
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood access device and accessories
Regulatory Class: Class II
Product Code: FIE

Dear Sho Hosoki:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change for your device cleared on August 15, 2025. Specifically, FDA is updating this substantial equivalence (SE) letter to correct the official correspondent as an administrative correction.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Maura Rooney, OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices, 781-587-7531, Maura.Rooney@fda.hhs.gov.

Sincerely,

Maura Rooney -S

Maura Rooney
Assistant Director
DHT3A: Division of Renal, Gastrointestinal, Obesity, and Transplant Devices
OHT3: Office of Gastrorenal, ObGyn, General Hospital, and Urology Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

August 15, 2025

JMS North America Corporation
Sho Hososki
Director QA/RA
22320 Foothill Blvd. Suite 350
Hayward, California 94541

Re: K251877
Trade/Device Name: JMS CAVEO A.V. Fistula Needle Set
Regulation Number: 21 CFR 876.5540
Regulation Name: Blood Access Device And Accessories
Regulatory Class: Class II
Product Code: FIE
Dated: June 18, 2025
Received: June 18, 2025

Dear Sho Hososki:

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,

Maura Rooney -S

Maura Rooney
Assistant Director
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Office of Product Evaluation and Quality
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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)*
K251877

Device Name
JMS CAVEO A.V. Fistula Needle Set

Indications for Use *(Describe)*
JMS CAVEO A.V. Fistula Needle Set is intended for temporary cannulation to vascular access for extracorporeal blood treatment for hemodialysis. This device is intended for single use only. The anti-needlestick safety feature aids in prevention of needle stick injuries when removing and discarding the needle after dialysis. The device also has an integrated safety mechanism that is designed to automatically generate a partial occlusion of the internal fluid path and trigger the hemodialysis machine to alarm and shut off if a complete dislodgement of the venous needle from the arm inadvertently occurs. In vitro testing supports that this feature triggers the hemodialysis machine to alarm and shut off.

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.

Section 05: 510(k) Summary [807.92(c)]

Owner [807.92(a)(1)]:

Company Name: JMS North America Corp.
Company Address: 22320 Foothill Blvd., Suite 350
Hayward, CA 94541
Telephone: 510-888-9090
Fax: 510-888-9099
Contact Person: Sho Hosoki
Summary Preparation Date: 08/07/2025

Device of Submission [807.92(a)(2)]

Classification Name: Blood access device and accessories
Common/Usual Name: Needle, Fistula
Proprietary Name: JMS CAVEO A.V. Fistula Needle Set
Classification: Class II
Product Code: FIE
Code of Federal Regulations: 21 CFR 876.5540

Predicate Device [807.92(a)(3)]

K Number	Product	Company	Predicate/Reference
K111948	JMS A.V. Fistula Needle Set WingEater®	JMS North America Corporation	Predicate
K142564	SysLoc® MINI (V4)	JMS North America Corporation	Reference

Device Description [807.92(a)(4)]

The subject device is the JMS CAVEO A.V. Fistula Needle Set (CAVEO) with an anti-needlestick safety feature. The Caveo is predicted to protect patients from the risks associated with venous needle dislodgement (VND) based on bench testing results. It contains an integrated stainless steel torsion spring mechanism and bottom footplate that provides an open/fluid path when the AV fistula set is fully cannulated into the access site. When the venous needle becomes completely dislodged from the patient's arm, this mechanism enables the footplate to partially occlude the blood path, generating an increased venous line pressure high enough to trigger automatic alarm and halt further blood pumping of the hemodialysis machine. In vitro testing supports that this feature triggers the hemodialysis machine to alarm and shut off. Based on bench testing results, this may significantly reduce patient blood loss in the event of a complete VND. The Caveo has a pre-attached anti-stick needle guard for prevention of needlestick injury at the time of needle withdraw after completion of a hemodialysis procedure.

In vitro performance testing using dialysis machine Fresenius 2008K supports the function of the Caveo VND feature with a venous pressure limit set to 200mmHg symmetric mode, a maximum dialyzer membrane surface area of 2.5 m2, minimum blood flow rate of 200 mL/min, maximum ultrafiltration rate of 4000 mL/hour, and simulated treatment duration of 8 hours. If

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different machine and/or setting are used, before introducing the device, refer to Directions for Use.

Intended Use [807.92(a)(5)]

Indications for Use:
JMS CAVEO A.V. Fistula Needle Set is intended for temporary cannulation to vascular access for extracorporeal blood treatment for hemodialysis. This device is intended for single use only. The anti-needlestick safety feature aids in prevention of needle stick injuries when removing and discarding the needle after dialysis. The device also has an integrated safety mechanism that is designed to automatically generate a partial occlusion of the internal fluid path and trigger the hemodialysis machine to alarm and shut off if a complete dislodgement of the venous needle from the arm inadvertently occurs. In vitro testing supports that this feature triggers the hemodialysis machine to alarm and shut off.

Predicate Comparison [807.92(a)(6)]

	Modified Device	Predicate
Device Name	JMS CAVEO A.V. Fistula Needle Set	WingEater®
510(k) #	K233685	K111948
Classification	Class II	Class II
Indication for use/Intended Use	Intended Use: Symptoms requiring blood purification such as acute renal failure and chronic renal failure. Indications for Use: JMS CAVEO A.V. Fistula Needle Set is intended for temporary cannulation to vascular access for extracorporeal blood treatment for hemodialysis. This device is intended for single use only. The anti-needlestick safety feature aids in prevention of needle stick injuries when removing and discarding the needle after dialysis. The device also has an integrated safety mechanism that is designed to automatically generate a partial occlusion of the internal fluid path and trigger the hemodialysis machine to alarm and shut off if a complete dislodgement of the venous needle from the arm inadvertently occurs. In vitro testing supports that this feature triggers the hemodialysis machine to alarm and shut off.	Use for temporary cannulation for vascular access for extracorporeal blood treatment. The device is intended to single use only and is for temporary catheterization less than 30 days. The safety feature (foldable wing and WingEater guard) aids in prevention of needlestick injuries when removing and discarding needle after dialysis session
Physical Specification		
Distal End Configuration	Cannula	Cannula

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Cannula Gauge	14G, 15G, 16G, 17G	14G, 15G, 16G, 17G, 18G
Cannula Exposed Length	1'' & 1 ¼"	1'' & 1 ¼"
Cannula Type	Sharp & Blunt With & without Back Eye (BE)	Sharp With & without Back Eye (BE)
Wing Colour	14G: Translucent White 15G: Translucent Blue 16G: Translucent Green 17G: Translucent Orange	14G: White 15G: Blue 16G: Green 17G: Orange 18G: Pink
Clamp Colour	White, Blue	White, Red, Blue
Tube Length	270mm (12") & 400mm (16")	135mm (6") & 270mm (12")
Proximal End Configuration	Female Luer Lock	Female Luer Lock
Special Features	Caveo contains an internal core with a flexible membrane, an underlying footplate and a torsion spring that enable the VND detection and machine shut-off functionality. Anti-needlestick safety feature of Caveo is a needle guard pre-attached onto tubing to encapsulate needle within the guard upon completion of hemodialysis session.	Retract wing into WingEater guard after removing needle. Wing and needle slides into the WingEater and lock in position to prevent needle stick.
Performance Specification	Upon complete VND, the opening of Caveo footplate partially occluded the internal flow path, increased venous line pressure and triggered upper alarm limit of dialysis machine. Caveo required very minimum force when retraction and needle is locked after use. Caveo needle guard will not be punctured by needle when properly used.	WingEater guard will not be punctured by needle when properly used. WingEater guard is able to be operated by one hand and two-handed techniques.
Technical Characteristic of Anti-stick	Retract needle into Caveo needle guard. Needle slides into the needle guard and locks in position to prevent needle stick.	Retract wing into WingEater guard after removing needle. Wing and needle slides into the WingEater guard and lock in position to prevent needle stick.
Material	Described in biocompatibility section	
Labeling	Attached in "Substantial Equivalence Comparison – Label"	
Sterilization	ETO sterilization	ETO sterilization
Functional Specification		
Needle Penetration Resistance	14G: ≤ 40g 17G: ≤ 30g 15G: ≤ 35g 16G: ≤ 30g	14G: ≤ 40g 17G: ≤ 30g 15G: ≤ 35g 18G: ≤ 25g 16G: ≤ 30g
Needle Retention Strength	> 6.0kgf	> 6.0kgf

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Needle Surface (Visually)	No dented / damaged needle	No dented / damaged needle
Product Leak	When subjected to air pressure 0.40 kgf/cm^2 and immersed in water, air bubble should not appear.	When subjected to air pressure 0.40 kgf/cm^2 and immersed in water, air bubble should not appear.
Needle Retraction Final Lock Strength	≤ 2.0kgf	≤ 2.0kgf
Connector	1. Air tightness is tested by ISO 80369-7. 2. Luer meets ISO 80369-7.	1. Air tightness is tested by ISO 594-2. 2. Luer meets ISO 594-1.
Connection Strength	1. Tube to Connector/Joint: > 6.0kgf 2. Tube to Pivot Valve Core: > 6.0kgf	1. Tube to Connector/Joint: > 3.0kgf 2. Tube to Hub: > 6.0kgf

Nonclinical Tests [807.92(b)(1)]

Biocompatibility

Requirement	Applicable Standard	Result
Cytotoxicity	ISO 10993-5	Passed
Sensitization	ISO 10993-10	Passed
Irritation or Intracutaneous reactivity	ISO 10993-10	Passed
Hemocompatibility	ISO 10993-4	Passed
Material-mediated pyrogenicity	ISO 10993-11	Passed
Acute systemic toxicity	ISO 10993-11	Passed
Subacute toxicity	ISO 10993-11	Passed
Genotoxicity	ISO 10993-3	Passed

Performance

Test	Result
For Female Luer Lock Connector (ISO 80369-7)	
1) Leakage by Pressure Decay	Passed
2) Positive Pressure Liquid Leakage	Passed
3) Sub-atmospheric Pressure Air Leakage	Passed
4) Stress Cracking	Passed
5) Resistance to Separation from Axial Load	Passed
6) Resistance to Separation from Unscrewing	Passed
7) Resistance to Overriding	Passed
8) Tube to Connector Pull Test	Passed
9) Luer Lock Cover Open Torque Test	Passed
For Anti-Needlestick Safety Feature of Caveo	
1) Testing Activation of the Sharps Injury Protection Feature	Passed
2) Needle Pushback Strength Test	Passed

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3) Needle Guard Detachment Strength Test	Passed
For Caveo	
1) Appearance Check	Passed
2) Cover Pull with Hub	Passed
3) Air Leak Test	Passed
4) Positive Pressure Leak Test	Passed
5) Negative Pressure Leak Test	Passed
6) Needle Guard Retraction Final Lock Test	Passed
7) Tube to Hub Pull Test	Passed
8) Cannula to Hub Tensile Test	Passed
9) Dimensional Analysis of Footplate to Pivot Valve Core	Passed
10) TPE Front & Back Ends Internal Diameter (Y-axis) Measurements	Passed
11) TPE Surface Roughness	Passed
12) Cannulation at 15 and 45-Degree Angles	Passed
13) Occlusion After Taping	Passed
14) VND Performance	Passed
15) Baseline Pressure Comparison	Passed
16) Force to Depress the Footplate	Passed
17) Mechanical Hemolysis Testing	Passed
18) Simulated Clinical Usability Study	Successful
19) Transportation Test	Passed
20) Human Factors Testing	Passed

Clinical Trial Test [807.92(b)(2)]

Clinical trial testing was conducted on patients to confirm the safety, performance and usability of CAVEO.

A total of 15 subjects were recruited from the general hemodialysis population. 2 females (both are not Hispanic or Latino; one is native Hawaiian or other Pacific Islander and the other is White) and 13 males (10 of them are Hispanic or Latino and the rest are not; one is Black or African American and the rest are White).

Based on results of this trial, the CAVEO is capable of delivering prescribed hemodialysis. The novel components of the CAVEO designed to protect against VND (particularly the underlying footplate) did not impede the safe, normal, and efficacious delivery of prescribed hemodialysis.

Conclusion [807.92(b)(3)]

JMS CAVEO A.V. Fistula Needle Set has substantial equivalence with the predicate in intended use and technological characteristics. However, Caveo has additional novel VND safety mechanism and different anti-needlestick safety feature as well as some other minor differences. Clinical, human factors, biocompatibility and bench performance testing was conducted to verify that CAVEO is as safe, as effective, and performs equivalent to the

Section 05: 510(k) Summary [807.92(c)]

predicate if used as intended. Evaluation data and reports are enclosed within this submission document.