March 20, 2026

ICU Medical, Inc.
Akash Gouli
Associate III, Regulatory Affairs
951 Calle Amanecer
San Clemente, California 92673

Re: K251980
Trade/Device Name: ClaveQS™ Bag
Regulation Number: 21 CFR 880.5025
Regulation Name: I.V. Container
Regulatory Class: Class II
Product Code: KPE
Dated: February 19, 2026
Received: February 20, 2026

Dear Akash Gouli:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

DAVID WOLLOSCHECK -S

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K251980

Device Name
ClaveQS™ Bag

Indications for Use *(Describe)*
The ClaveQS™ Bag is intended for compounding and administration of parenteral solutions. Medication transfer in and out of the ClaveQS™ Bag is done using aseptic technique.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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510(k) #: K251980

510(k) Summary

Prepared on: 2026-03-19

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	ICU Medical, Inc.
Applicant Address	951 Calle Amanecer San Clemente CA 92673 United States
Applicant Contact Telephone	551-804-0592
Applicant Contact	Mr. Jeffrey Wan
Applicant Contact Email	jeffrey.wan@icumed.com
Correspondent Name	ICU Medical, Inc.
Correspondent Address	951 Calle Amanecer San Clemente CA 92673 United States
Correspondent Contact Telephone	551-297-9031
Correspondent Contact	Mr. Akash Gouli
Correspondent Contact Email	akash.gouli@icumed.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	ClaveQS™ Bag
Common Name	I.V. container
Classification Name	Container, I.V.
Regulation Number	880.5025
Product Code(s)	KPE

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K201936	SmartSite Bag	KPE

Device Description Summary

21 CFR 807.92(a)(4)

The ClaveQS™ Bag is an empty EVA container with integral Clave and/or administration set ports. Clave is a needlefree, bi-directional connector that utilizes a pre-slit septum which prevents microbial ingress for seven (7) days and up to 400 activations. The septum offers neutral displacement of fluid during connection or disconnection of a male luer and self seals upon disconnect to prevent fluid loss or air ingress. The Clave will passively aid in the prevention of needlestick injuries.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The ClaveQS™ Bag is intended for compounding and administration of parenteral solutions. Medication transfer in and out of the ClaveQS Bag is done using aseptic technique.

Indications for Use Comparison 21 CFR 807.92(a)(5)

Both the subject ClaveQS™ Bag and predicate SmartSite Bag share the indication for administration of IV solutions using aseptic technique.

The subject device has indications for compounding and administration of other parenteral fluids, which are not present in the predicate device. The predicate device is specifically indicated for use with an IV admin set.

These differences do not change the general intended use of the subject device for administration of fluids. As such, the subject device is determined to be substantially equivalent to the predicate device in the indications for use.

Technological Comparison 21 CFR 807.92(a)(6)

The subject device ClaveQS™ Bag and predicate device SmartSite Bag are comprised of an empty bag and two ports. The subject device comes in two configurations: 1) one add port + one spike port, and 2) two add ports. The predicate device comes in a single configuration with one add port and one spike port. The difference in the port options do not impact the ability of the subject device to administer fluids aseptically.

Both devices share the same sterilization method--irradiation to a SAL of 10^-6. The subject device is provided sterile, while the predicate device is sterile fluid path. Both devices ensure that medication is not contaminated when administered to a patient.

Both devices are intended for single-use only.

The devices differ in their materials of construction. Biocompatibility testing was conducted to demonstrate substantial equivalence in safety.

Non-Clinical and/or Clinical Tests Summary & Conclusions 21 CFR 807.92(b)

The subject device ClaveQS™ Bag is categorized as an externally communicating device with indirect blood path contact for a prolonged duration. Biocopmatibility testing was conducted in accordance with ISO 10993-1:2018 and the FDA Guidance “Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices Part 1: Evaluation and testing within a risk management process”, issued September 8, 2023.

Non-clinical verification testing has been conducted to demonstrate the functionality of the ClaveQS™ Bag over the course of its shelf-life.

Performance of the IV container was evaluated in accordance with ISO 15747, along with additional tests for assembly integrity and infusate compatibility.

Performance of the Clave ports was evaluated in accordance with ANSI/AAMI CN27, ISO 8536-4, ISO 80369-7, and USP <788>. Additional testing include exposure to CHG, disinfectant cap compatibility, and seal return testing.

No clinical testing was used in support of this submission

The results of the performance testing described in this section supports a substantial equivalence determination to the predicate device.