December 23, 2025

HAI Solutions
% Roshana Ahmed
President
Quaras, LLC
2101 Camino Rey
Fullerton, California 92833

Re: DEN250004
Trade/Device Name: QIKCAP System
Regulation Number: 21 CFR 880.6512
Regulation Name: Ultraviolet light-based microbial reduction device for luer-activated valves
Regulatory Class: Class II
Product Code: SGX
Dated: January 30, 2025
Received: January 30, 2025

Dear Roshana Ahmed:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your De Novo request for classification of the QIKCAP System, a prescription device under 21 CFR Part 801.109 with the following indications for use:

> The HAI Solutions QIKCAP Device, used in conjunction with the single-use QIKCAP Cap, is a UVC treatment device intended to supplement manual needle-free luer connector instructions to 'scrub the hub' with CHG/IPA wipes. After conducting the protocol in the needle-free connector instructions for use, the QIKCAP Device applies UVC to the connector septum for 10 seconds to assist in reducing microbial contamination. The single use QIKCAP Cap also functions as a physical barrier, helping protect the connector from environmental contamination for up to 7 days if not removed.
>
> Under the conditions of testing, the combined use of an 3.15% CHG/70% IPA wipes applied for a 5 seconds and the QIKCAP Device resulted in 4-log reductions in Staphylococcus aureus, Klebsiella pneumoniae, Staphylococcus epidermidis, and Enterobacter cloacae.
>
> The device has not shown a significant reduction in fungal organisms.
>
> A correlation to clinical infection-related outcomes has not been established.

FDA concludes that this device should be classified into Class II. This order, therefore, classifies the QIKCAP System, and substantially equivalent devices of this generic type, into Class II under the generic name ultraviolet light-based microbial reduction device for luer-activated valves.

FDA identifies this generic type of device as:

> **Ultraviolet light-based microbial reduction device for luer-activated valves**. An ultraviolet light-based microbial reduction device for luer-activated valves is a device that uses ultraviolet light to irradiate luer-activated valves (e.g., as used for intravascular administration). The device is intended to supplement the manual, physical microbicidal treatment of luer-activated valves by providing limited microbial reduction, and is not intended to disinfect or replace manual microbicidal treatment.

Section 513(f)(2) of the Food, Drug and Cosmetic Act (the FD&C Act) was amended by section 607 of the Food and Drug Administration Safety and Innovation Act (FDASIA) on July 9, 2012. This law provides two options for De Novo classification. First, any person who receives a "not substantially equivalent" (NSE) determination in response to a 510(k) for a device that has not been previously classified under the Act may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. On December 13, 2016, the 21st Century Cures Act removed a requirement that a De Novo request be submitted within 30 days of receiving an NSE determination. Alternatively, any person who determines that there is no legally marketed device upon which to base a determination of substantial equivalence may request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act without first submitting a 510(k). FDA shall, within 120 days of receiving such a request, classify the device. This classification shall be the initial classification of the device. Within 30 days after the issuance of an order classifying the device, FDA must publish a notice in the Federal Register announcing the classification.

On January 30, 2025, FDA received your De Novo requesting classification of the QIKCAP System. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the QIKCAP System into class I or II, it is necessary that the proposed class have sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the De Novo request, FDA has determined that, for the previously stated indications for use, the QIKCAP System can be classified in class II with the establishment of special controls for class II. FDA believes that class II (special) controls provide reasonable assurance of the safety and effectiveness of the device type. The identified risks and mitigation measures associated with the device type are summarized in the following table:

Identified Risks to Health	Mitigation Measures
Infection or spread of infection due to: • Device failure or otherwise inadequate microbial reduction effect • Use error • Inadequate reprocessing instructions	Non-clinical performance testing Reprocessing validation Software verification, validation, and hazard analysis Human factors testing Labeling
Tissue or ocular damage due to irradiation or byproducts from ultraviolet light exposure (e.g., ozone, reactive oxygen species)	Non-clinical performance testing
Device degradation due to time or usage cycles leading to reduced or compromised functionality, whether the device or the reprocessed device	Non-clinical performance testing Shelf life and use life testing Labeling
Electrical shock or interference with other electrical components	Electrical safety testing Electromagnetic compatibility testing

In combination with the general controls of the FD&C Act, the ultraviolet light-based microbial reduction device for luer-activated valves is subject to the following special controls:

(1) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including the following:
   (i) Design verification testing to ensure the device meets its design specifications and performs as intended over its indicated shelf life and use life;
   (ii) Simulated use testing to demonstrate microbial reduction under worst-case conditions, including soiling and inoculation with clinically relevant microorganisms throughout the shelf life and use life of the device;
   (iii) Ultraviolet light safety evaluation, including ocular safety and byproduct evaluation that includes quantification of potentially hazardous byproducts (e.g., ozone per 21 CFR 801.415, reactive oxygen species) generated during the treatment cycle and demonstration that any identified byproducts remain below established safety limits; and
   (iv) An assessment demonstrating that ultraviolet light exposure does not adversely affect neither the luer-activated valve's mechanical integrity or biocompatibility over its use life, nor the biocompatibility of the entrained fluid.

(2) Reprocessing validation, including cleaning validation and validation of an appropriate microbicidal process, must be performed for reusable components.

(3) Performance testing must demonstrate the electromagnetic compatibility (EMC) and electrical safety of the device in the intended use environment.

(4) Software verification, validation, and hazard analysis must be performed for all software components of the device.

(5) Human factors testing must demonstrate that the intended users can correctly and safely use the device for its intended use, based solely on its labeling.

(6) Labeling must include the following:
   (i) A summary of the device's technical parameters and performance specifications;

(ii) Validated reprocessing instructions;
(iii) Shelf life and/or use life information;
(iv) A statement regarding user adherence to both the luer-activated valve manufacturer's instructions for use and the manufacturer's instructions for use for any physical processing devices used on the luer-activated valve;
(v) Instructions for any required maintenance; and
(vi) Information about the luer-activated valves that can be used with the device.

In addition, this is a prescription device and must comply with 21 CFR 801.109.

Although this letter refers to your product as a device, please be aware that some granted products may instead be combination products. If you have questions on whether your product is a combination product, contact CDRHProductJurisdiction@fda.hhs.gov.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device type. FDA has determined premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device type and, therefore, the device is not exempt from the premarket notification requirements of the FD&C Act. Thus, persons who intend to market this device type must submit a premarket notification containing information on the ultraviolet light-based microbial reduction device for luer-activated valves they intend to market prior to marketing the device.

Please be advised that FDA's decision to grant this De Novo request does not mean that FDA has made a determination that your device complies with other requirements of the FD&C Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the FD&C 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 FD&C Act; 21 CFR 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.

A notice announcing this classification order will be published in the Federal Register. A copy of this order and supporting documentation are on file in the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852 and are available for inspection between 9 a.m. and 4 p.m., Monday through Friday.

As a result of this order, you may immediately market your device as described in the De Novo request, subject to the general control provisions of the FD&C Act and the special controls identified in this order.

For comprehensive regulatory information about medical devices and radiation-emitting products, 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).

If you have any questions concerning the contents of the letter, please contact Dana Rottach at dana.rottach@fda.hhs.gov.

Sincerely,

CHRISTOPHER K. DUGARD -S

Christopher K. Dugard, M.S.
Director
DHT4C: Division of Infection Control Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
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