DE NOVO CLASSIFICATION REQUEST FOR QIKCAP SYSTEM

REGULATORY INFORMATION

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.

NEW REGULATION NUMBER: 21 CFR 880.6512

CLASSIFICATION: CLASS II

PRODUCT CODE: SGX

BACKGROUND

DEVICE NAME: QIKCAP System

SUBMISSION NUMBER: DEN250004

DATE DE NOVO RECEIVED: January 30, 2025

SPONSOR INFORMATION:
HAI Solutions
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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 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.

LIMITATIONS

The QIKCAP System is intended to be marketed for Prescription (RX) use.

Please refer to the labeling for a complete list of warnings, precautions and contraindications.

DEVICE DESCRIPTION

The QIKCAP System is an adjunct ultraviolet light-based microbial reduction device for luer-activated valves and associated caps to provide a barrier to continued contamination of the luer-activated valve.

The device consists of the reusable handheld QIKCAP Device and the single use provided-sterile QIKCAP Cap. The cap is placed on a luer-activated valve after the connector is processed with the "Scrub the Hub" microbial reduction technique using wipes with CHG and alcohol, as specified in its labeling. The QIKCAP Device produces light nominally at 265 nm, in the UVC range (ultraviolet light between approximately 200 to 280 nm). The handheld device is then placed over the cap, activating a ten-second illumination of the UVC transparent cap, providing an additional microbial reduction over the manual processing alone.

The microbicidal performance of the QIKCAP Device was demonstrated with 3.15% CHG/70% IPA wipes following 5 seconds of scrubbing. The QIKCAP Device should only be used with compatible luer-activated valves that have compatible instructions for processing with corresponding IPA/CHG wipes.

QIKCAP Device

The sponsor provided the following product images:



Figure 1 The QIKCAP Device



Figure 2 The QIKCAP System, including the handheld QIKCAP Device and single-use sterile QIKCAP Caps

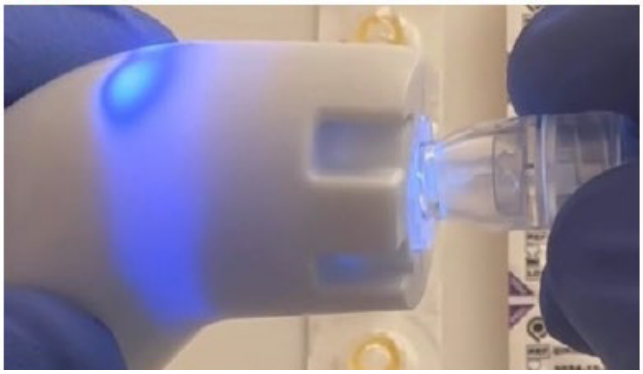


Figure 3 QIKCAP Device in operation, applying UVC light to a capped luer connector

SUMMARY OF NONCLINICAL/BENCH STUDIES

REPROCESSING, STERILITY AND SHELF-LIFE

The QIKCAP Cap is for single use and is provided sterilized by a validated ethylene oxide process. The sterilization validation for Ethylene Oxide (EO) sterilization was performed in accordance with ISO 11135:2014, ISO 11138-7:2019, ISO 10993-7:2008, and ISO 11737-2:2020. The validation employed an overkill method, including fractional and full EO cycles, using Bacillus atrophaeus spores to demonstrate a sterility assurance level (SAL) of 10^{-6} for both maximum and minimum load configurations. Ethylene oxide (EO) and ethylene chlorohydrin (ECH) residuals were determined to be within acceptable "prolonged exposure" use limits after aeration. Limulus amebocyte lysate (LAL) testing was used to confirm acceptable bacterial endotoxin levels in accordance with AAMI ST-72:2019. Packaging validation was performed according to ISTA Procedure 2A and ASTM D642-15, ASTM D999-08, and ASTM D5276-98 standards, to confirm sterile barrier system integrity under worst-case temperature, humidity, compression, and vibration.

A one-year shelf life for the QIKCAP Caps is supported by a demonstration that real-time aged caps continue to meet all performance specifications.

The exterior of the reusable QIKCAP Device component of the QIKCAP System must be cleaned with a mild-alkaline enyzmatic detergent (Neodisher MediClean Forte) and disinfected with a low-level disinfectant (Super Sani-Cloth) wipe after use. The cleaning was validated using British Soil (BRSO) verified with protein and total organic carbon. The disinfection process was validated through individually testing four appropriate bacterial challenges in triplicate, which demonstrated greater than six-log reduction. The cleaning and disinfection methods were validated in accordance with AAMI TIR12:2020/(R)2023 "Designing, testing, and labeling medical devices intended for processing by health care facilities: A guide for device manufacturers" and Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling Guidance for Industry and Food and Drug Administration Staff Document issued on: March 17, 2015 Appendix E of this guidance was updated on June 9, 2017.

The shelf life of one year and a cycle life for the QIKCAP Device has been supported by a demonstration that the real-time aged devices and performance of 26,280 cycles (exceeding worst-case usage for one year) continue to meet all performance specifications.

BIOCOMPATIBILITY

The QIKCAP Cap demonstrated adequate biocompatibility in accordance with ISO 10993-1 Biological evaluation of medical devices" and FDA guidance "Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process,' Guidance for Industry and Food and Drug Administration Staff" when assessed using criteria for surface-contacting less than 30 day skin contact, including cytotoxicity (MEM elution), sensitization (GPMT), and intracutaneous irritation.

The impact of use of the device on the biocompatibility of the luer-activated valves was also investigated using luer-activated valves manufactured with materials representative of clinically available luer-activated valve. Material mediated pyrogenicity and hemolysis were acceptable, and a toxicological risk assessment did not identify additional risks.

The QIKCAP System underwent UVC radiation safety testing following IEC 62471 "Photobiological safety of lamps and lamp systems" and International Commission on Non-Ionizing Radiation (ICNIRP) guidelines, with a safe limit of 3 mJ/cm² for 8-hour UV exposure. Testing included three components: UVC leakage through the QIKCAP Cap during operation, radiation escape around uncapped IV connectors, and sensor verification to confirm the dual optical sensor switches prevent UVC emission unless the cap is properly engaged. Measurements taken at both 20 cm (standard evaluation distance) and 1 cm (extreme proximity). Results demonstrated no detectable UVC leakage. The device's safety interlocks were confirmed to be effective.

SOFTWARE & CYBERSECURITY

The QIKCAP Device includes minimal software for charging and timing and was identified as minimal risk.

Basic Documentation was provided and found acceptable.

The device has no external communication capability. Cybersecurity testing was conducted per FDA guidance documents, "Cybersecurity in Medical Devices: Quality System Considerations and Content of Premarket Submissions" and the results were found acceptable.

ELECTROMAGNETIC COMPATIBILITY & ELECTRICAL SAFETY

The device does not present probable risks of deaths or serious injuries due electromagnetic interference. Electrical safety testing of the QIKCAP Device was completed in accordance with IEC 60601-102.

COMPATIBILITY TESTING

The sponsor performed compatibility testing within a lifetime cycle study to evaluate potential damage to the functionality of the luer-activated valves following repeated usage. At the completion of the study, results demonstrated compatibility with luer-activated valves for 200 processing cycles, exceeding the worst-case expected number of accesses for a luer-activated valve.

HUMAN FACTORS TESTING

Summative and supplementary human factors testing were performed (which included studies in a simulated use environment to support the use-safety and effectiveness of use of the QIKCAP System. The studies evaluated use of the device, and accessed modifications to the device user interface, labeling and training. At the completion of testing, residual risks were demonstrated to be acceptable.

PERFORMANCE TESTING - BENCH

The sponsor conducted the following performance tests to support that the device can achieve its intended use:

Microbial Reduction Testing

Microbial reduction testing was performed both using the subject device and combined scrubbing with a chlorhexidine gluconate (CHG)/isopropyl alcohol (IPA) wipe on soiled and inoculated connectors to represent worst-case clinical conditions of use and through a separate study using inoculated luer-activated valves without soiling to characterize the effect of the device alone without the effect of the "scrub the hub" technique.

The study of the full, combined protocol evaluated the total microbial reduction achieved when using the CHG/IPA wipe followed by the QIKCAP Device, representing the

complete and recommended clinical procedure for the system. A 5-second scrub with a CHG/IPA wipe was selected to represent the 'worst-case' scrub time which is significantly shorter than the 10-15 second or longer scrub commonly recommended. Optimally done, manual scrubbing with a CHG/IPA wipe is expected to achieve a 4 log reduction of microorganisms. The measured microbial reductions from experimental testing of the full combined protocol exhibit an expected variability, which stems from a combination of inconsistent manual performance during the "scrub the hub" step and the inherent statistical challenges of measuring further log reductions when microbial counts are already very low. The full combined protocol demonstrated a greater than 4 log microbial reduction for Staphylococcus aureus, Klebsiella pneumoniae, Staphylococcus epidermidis, and Enterobacter cloacae.

Additional testing of the device performance without the "scrub the hub" technique confirmed that the UVC device is independently capable of at least 4 log microbial reduction on an unsoiled but inoculated surface (approximating a post-wipe state) for the same organisms, justifying that the device provides a distinct and likely additional benefit that contributes to the overall efficacy when used in conjunction with "scrub the hub."

Considering the totality of the testing, which evaluated both the use of the QIKCAP device alone and also in combination with a 3.15% CHG/70% IPA wipe applied for a 5 seconds wipe protocol (the minimum full protocol in accordance with labeling), the totality of the testing demonstrates/supports the device provides a likely benefit of additional reductions of Staphylococcus aureus, Klebsiella pneumoniae, Staphylococcus epidermidis, and Enterobacter cloacae when used with the full combined protocol as specified in device labeling. labeling.

Cap Barrier Performance

The QIKCAP Cap process indicator (class 1 chemical indicator) was verified to meet ISO 11140-1:2014 compliance. The device retained its initial color under exposure to sunlight, demonstrated that the color changed before the cycle finished, demonstrated that real-time aged caps retained their performance throughout their shelf life (one year), and demonstrated that the caps retained their indication throughout the use life of the cap (up to seven days).

Mechanical cap torque performance was verified through compliance with ISO 80369-7 "Small-bore connectors for liquids and gases in healthcare applications, Part 7: Connectors for intravascular or hypodermic applications" unscrewing torque requirements.

Barrier performance was verified using ISO 11607-1 "Packaging for terminally sterilized medical devices" method using aerosolized Bacillus atrophaeus spores. No penetration was observed.

LABELING

The labeling consists of product labels and folded Instructions For Use.

Labeling for this device is in accordance with the special controls listed below.

RISKS TO HEALTH

The table below identifies the risks to health that may be associated with use of ultraviolet light-based microbial reduction devices for luer-activated valves and the measures necessary to mitigate these risks.

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

SPECIAL CONTROLS

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.

BENEFIT-RISK DETERMINATION

Benefits

The primary benefit of the QIKCAP System is the supplemental reduction of microbial contamination on luer-activated valves after UV processing and manual scrubbing with a CHG/IPA wipe in accordance with luer activated valve instructions. Microbial contamination of the luer activated valve is one documented source of patient bloodstream infection. The QIKCAP cap also provides a physical barrier to recontamination for up to 7 days.

Risks

The primary risks include ineffective microbial reduction if the device is used improperly (e.g., without conforming to the luer-activated valve instructions for manual scrubbing with CHG/IPA wipes), which could lead to a false sense of security that the luer-activated valve has been adequately treated and thereby increase risk of patient infection. Reduction of fungi remains dependent upon appropriate manual processing.

Patient Perspectives
This submission did not include specific information on patient perspectives for this device.

Benefit/Risk Conclusion
As an adjunctive device to manual luer-activated valve scrubbing with 3.15% CHG/70% IPA wipes, the QIKCAP System demonstrates a four-log reduction of the four tested bacteria under the conditions of testing and provides persistent barrier protection for up to 7 days if not removed. The benefit of this microbial reduction appears to outweigh the examined mitigated risks. A clinical benefit in terms of any effect on bloodstream infections cannot be measured or predicted.

The QIKCAP System is not intended to perform as a disinfection cap system. The QIKCAP System does not provide any removal of soil, and is not meant to achieve disinfection. The system is intended only to use UVC treatment to provide an additional microbial reduction after the physical removal and treatment of bioburden on luer-activated valves that takes place with 3.15 % CHG 70% /IPA wiping according to the luer-activated valves instructions for use. Following treatment with the QIKCAP UV System, application of the QIKCAP cap to the luer-activated valve does not convey on-going microbicidal activity.

In conclusion, given the available information above, for the following indication statement:

> 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.
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>
> The device has not shown a significant reduction in fungal organisms.
>
> A correlation to clinical infection-related outcomes has not been established.

The probable benefits outweigh the probable risks for the QIKCAP System. The device provides probable benefits, and the probable risks can be reduced using general controls and the identified special controls.

CONCLUSION

The De Novo request for the QIKCAP System is granted and the device is classified as follows:

Product Code: SGX
Device Type: Ultraviolet light-based microbial reduction device for luer-activated valves
Regulation Number: 21 CFR 880.6512
Class: II