

**EVALUATION OF AUTOMATIC CLASS III DESIGNATION (DE NOVO) FOR
VIUGUARD SELF-SANITIZING KEYBOARD**

REGULATORY INFORMATION

FDA identifies this generic type of device as:

Ultraviolet radiation (UV) chamber disinfection device. An ultraviolet radiation (UV) chamber disinfection device intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation. This classification does not include self-contained open chamber UV disinfection devices intended for whole room disinfection in a healthcare environment.

NEW REGULATION NUMBER: 21 CFR 880.6600

CLASSIFICATION: II

PRODUCT CODE: OSZ

BACKGROUND

DEVICE NAME: VIUGUARD SELF-SANITIZING KEYBOARD (MODEL UVKB50)

SUBMISSION NUMBER: DEN100013

DATE OF DE NOVO : NOVEMBER 2, 2010

**REQUESTOR'S CONTACT: VIUGUARD
401 PARKPLACE CENTER, SUITE 200
KIRKLAND, WASHINGTON 98033**

REQUESTOR'S RECOMMENDED CLASSIFICATION: II

INDICATIONS FOR USE

Indicated for use in a healthcare environment to reduce microbial populations typically found on a computer keyboard.

Device Effectiveness

In laboratory testing, the Vioguard UVKB50 Self-Sanitizing Keyboard has been shown to be effective at reducing populations of the following microorganisms when operated at its factory power setting of 240 mW-s/cm²:

- *Escherichia coli*
- *Pseudomonas aeruginosa*
- *Staphylococcus aureus*

- *Klebsiella pneumonia*

LIMITATIONS

Limitations on device use are also achieved through the following statements included in the Instructions for Use Manual, as well as the applicable special controls:

Warning: Do not use the Vioguard UVKB50 for disinfecting any other objects. The Vioguard UVKB50 is a self-sanitizing keyboard and not intended for any other use.

Warning: Failure to properly set up, use, and care for the Vioguard UVKB50 can increase the risk of serious injury or death, or damage to the Vioguard UVKB50. Read the manual for important safety and health information.

Warning: DO NOT pour any liquid cleaner or disinfectant directly on any surface of the Vioguard UVKB50.

Warning: No User-Serviceable Parts Inside; Do not attempt to take apart, open, service or modify the internal components of the Vioguard UVKB50.

Caution: When visibly dirty the effectiveness of the disinfection cycle might be inhibited.

Danger: Do not use any flammable or combustible liquids to clean the Vioguard UVKB50.

Danger: The Vioguard UVKB50 employs a powerful UV-C lamp source to kill germs. Light from the UV-C lamp should never be visible to the user.

Danger

- Ultraviolet (UV-C) Radiation Hazard
- Any exposure may cause significant eye damage and may cause skin damage
- Do not look into UV-C light source

PLEASE REFER TO THE LABELING FOR A MORE COMPLETE LIST OF WARNINGS AND CAUTIONS.

DEVICE DESCRIPTION

The Vioguard self-sanitizing keyboard, or UVKB50, is a keyboard with touchpad which resides in a motorized tray. The tray retracts into an enclosed UV-C treatment device which irradiates the keyboard with UV-C light of ~ 254 nm wavelength generated by two 25 watt ultraviolet germicidal lamps. The device includes dual safety interlocks intended to prevent operation of the UV lamps unless the keyboard is fully retracted into the unit and the unit door is completely closed. This feature is intended to prevent the device user from exposure to UV-C light. The device operations are controlled by a small 8-bit microcontroller. Reading instructions and data stored permanently in its own internal memory and controlling the hardware directly, the tasks accomplished by device firmware/software are the following:

- Controlling the motorized slide by activating the DC motor and reading the limit

- switches which are part of the slide mechanism;
- Controlling the UV-C lamp exposure time, by reading the light sensor and integrating the dosage until a preset exposure is reached;
 - Determining the dosage setting by reading an internal potentiometer;
 - Controlling and reading the state of the proximity sensor;
 - Calibrating the light sensor at the factory and storing the calibration information in internal non-volatile memory;
 - Controlling the LED status indicator;
 - Determining if there is keyboard or touch pad activity; and
 - Monitoring the state of the front door.

The default disinfection cycle takes 80 to 120 seconds to complete.

A summary of the key device features is as follows:

ENCLOSURE:

The UVKB50 keyboard and touchpad are stored in a mechanized enclosure when not in use for keyboard data entry functions. Please refer to Figure 1 below; the diagram shows that the keyboard extends from the enclosure to allow for keyboard use. The enclosure is made of aluminum, which can be surface cleaned, and is designed to support a computer monitor on top to save desk space.

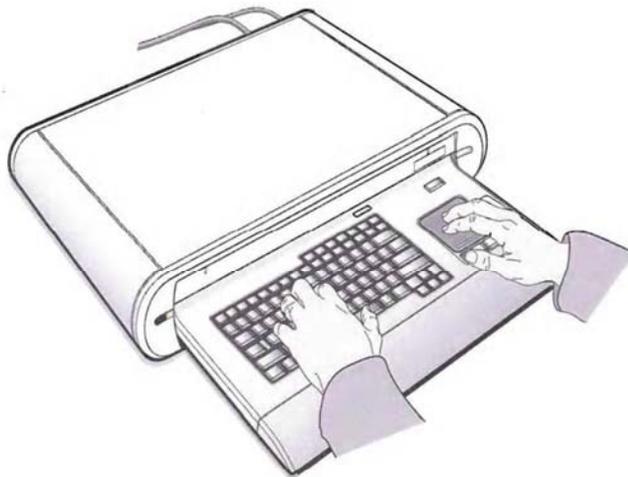


Figure 1: Vioguard unit with keyboard slide extended

TOUCHLESS SENSOR AND MOTORIZED DRAWER:

When the user sits at the computer workstation to use the keyboard, the user waves a hand near an infrared proximity sensor located on the enclosure's front panel. A reversible DC motor opens the enclosure's door when the sensor is activated and automatically extends the keyboard from the enclosure into a working position for the user.

AUTOMATIC/MANUAL UV-C DISINFECTION MODES:

The UVKB50 can be set to automatically retract the keyboard and run a disinfection cycle after a 10 minute period of keyboard inactivity, or when operated in the manual

mode. When the user is finished at the keyboard workstation, the user can manually initiate a disinfection cycle by pressing the “close” button on the keyboard. This causes the keyboard tray to retract into the enclosure and initiate a disinfection cycle.

DISINFECTION CYCLE:

Disinfection is performed using two 25-watt ultraviolet germicidal lamps. The UVKB50 electronics consist of a power supply and lamp ballast, which operate on standard AC (line) power. The reflector and diffuser inside the enclosure are used to distribute the light over the keyboard surface during a disinfection cycle. The ultraviolet light used is known as UV-C, at ~254 nm wavelength.

DISINFECTION CYCLE CONTROL:

Once inside the enclosure, the keyboard and touchpad are illuminated with the UV-C germicidal light. Software in the Vioguard UVKB50 monitors the output of the UV-C bulbs and adjusts the disinfection cycle duration. The default disinfection cycle takes 80 to 120 seconds to complete.

LED STATUS INDICATOR:

A multicolor LED status indicator on the enclosure’s front panel provides the device user with information on disinfection cycle completion, servicing needs, etc. For example: A green LED means the disinfection cycle has been completed and the keyboard is ready for use; a flashing red LED indicates that a UV bulb needs replacement, etc.

SAFETY INTERLOCKS:

When the keyboard tray is retracted into the enclosure, the enclosure’s spring-loaded front door shuts and the enclosure remains “light-tight.” The “light-tight” door has been designed to protect the user against inadvertent UV-C exposure.

SUMMARY OF NONCLINICAL/BENCH STUDIES/OTHER TESTING

Microbial Reduction Testing

Antimicrobial performance testing under simulated conditions of use for the device was performed by an independent laboratory. Using both gram positive and gram negative pathogens, the requestor provided adequate justification for the selection of test organisms. A wide range of microbes such as tubercle bacilli, streptococci, pneumococci and staphylococci have been demonstrated to be present on keyboards used in patient care areas. The requestor noted that the 4 bacteria studied, *Escherichia coli*, *Staphylococcus aureus*, *Pseudomonas aeruginosa* and *Klebsiella pneumonia* are major nosocomial pathogens, which can be transmitted by direct contact. The requestor also noted that all of the above bacteria are used by the Environmental Protection Agency (EPA) in its efficacy testing of disinfectants.

The independent laboratory studied the 4 pathogens listed above and the testing demonstrated that the device was effective at reducing populations of the 4 bacteria when operated at its factory power setting of b(4) . The organisms were

diluted b(4);
b(4) through a small syringe and allowed to dry for 45 to 50 minutes before treatment. The final antibacterial UV-C irradiation test data showed that the device achieves a 4.0 log₁₀ or greater reduction of each of the challenge pathogens at each of the "worst case" device sites irradiated. These results support the device claim to reduce the populations of the tested challenge pathogens by at least 4.0 log₁₀ CFU/ml.

Biocompatibility/Materials

Not applicable. The device is not patient-contacting.

Animal Studies

No animal testing was completed nor deemed necessary for the Vioguard self-sanitizing keyboard to support a reasonable assurance of safety and effectiveness.

Electrical and Mechanical Safety

The Vioguard self-sanitizing keyboard operates at 100-240 VAC, 80 watts, and 50/60 Hz. It has a microprocessor that controls the disinfection times and operation of the proximity sensor and motor, and monitors the safety interlock switches and lamp status. Two 25-watt germicidal fluorescent lamps provide output at 254 nm, resulting in disinfection of the keyboard and touch-pad. The lamp is designed to operate for 1-2 years with moderate use before needing a replacement.

The requestor conducted testing according to the following Agency recognized standards:

- IEC 60601-1: Medical electrical equipment - Part 1: General requirements for safety
- IEC 60601-1-2: Medical Electrical Equipment - Part 1-2: General Requirements for Safety; Electromagnetic Compatibility – Requirements and Tests

Testing conducted by an independent lab verified that the device meets IEC 60601-1 and IEC 60601-1-2. The electromagnetic compatibility tests included radiated emissions, surge, conducted immunity, electrical fast transient burst, voltage dips and interrupts. All the results demonstrate that the device passes the tests without any malfunction. The requestor provided data to demonstrate that atmospheric ozone generation is prevented by use of lamps designed to suppress ozone-generation wavelengths. In the event that ozone were generated, it would be necessary to meet the maximal acceptable level ozone in accordance with 21 CFR 801.415. Additionally, the requestor also provided certification from an independent lab that the device passed the Federal Communications Commission conducted emissions and radiated emissions test successfully. Based on the Agency recognized electrical safety standards which includes fire hazard testing, the requestor demonstrated electrical safety of the device.

SOFTWARE

The device firmware is a set of embedded instructions for a small, 8bit microcontroller which form a customized control system for the operation of the UVKB50. b(4)

b(4) . The instructions are contained in a nonvolatile internal flash memory and are potentially re-programmable by a service technician with the proper specialized equipment but not by an end user.

Per the recommendations of the FDA document, Guidance for the Content of Premarket Submission of Software Contained in Medical Devices” (dated 5/11/2005), the *de novo* included the following information:

- Level of concern (Minor)
- Software description
- Device/system level hazards analysis
- Software requirements specification
- Architecture design chart
- Software design specifications
- Traceability analysis/matrix
- Software development summary
- The results of verification and validation testing
- The revision level history (showing the latest revision level)
- Identification and description of all unresolved anomalies

Based on the identified level of concern, all necessary information was provided and deemed sufficient.

CLINICAL DATA

No clinical testing was provided nor deemed necessary for the Vioguard self-sanitizing keyboard UVKB50 to support a reasonable assurance of safety and effectiveness.

LABELING

The *de novo* contains appropriate Instructions for Use labeling and User’s Manual. The directions for use include the indications for use, setup instructions, product specifications, detailed operating instructions, appropriate contraindications/warnings/cautions statements, safety information, recommended cleaning procedures and disinfectants for cleaning the device. The Vioguard UVKB50 is available as an over-the-counter (OTC) device. The labeling adequately addresses the necessary information to ensure conformity with the special controls.

RISKS TO HEALTH

Table 1 identifies the risks to health associated with the use of Ultraviolet radiation (UV) chamber disinfection devices and the measures necessary to mitigate these risks.

Table 1 – Identified Risks and Mitigation Measures

Identified Risks	Mitigation Measures
Inadequate Equipment Disinfection	Performance Testing Labeling

Identified Risks	Mitigation Measures
UV Radiation Exposure	Performance Testing Labeling
Electrical Shock	Electrical Safety Testing
Electromagnetic Interference	Electromagnetic Compatibility (EMC) Testing Labeling
Ozone Exposure	Ozone Generation Limits Labeling
Processed Equipment Incompatibility	Performance Testing Labeling
Contamination of Device	Cleaning and Disinfection Validation Labeling
Software Malfunction	Hazard Analysis of Software Software Verification and Validation

SPECIAL CONTROLS

In combination with the general controls of the Food, Drug, and Cosmetic Act, the Ultraviolet radiation (UV) chamber disinfection device is subject to the following special controls:

1. Performance testing must demonstrate the following:
 - a. The chamber's ability to control the UV radiation dose during operation.
 - b. The chamber's disinfection performance through microbial challenge testing.
 - c. Evidence that the equipment intended to be processed is UV compatible.
 - d. Validation of the cleaning and disinfection procedures.
 - e. The ability of the device to continue to perform to all specification after cleaning and disinfection.
 - f. Whether the device generates ozone (if so, 21 CFR 801.415, Maximal acceptable level of ozone, applies).
2. Appropriate software verification, validation, and hazard analysis must be performed.
3. Appropriate analysis and/or testing must validate electrical safety, mechanical safety, and electromagnetic compatibility of the device in its intended use environment.
4. The labeling must include:
 - a. UV hazard warning labels.
 - b. Explanation of all displays and/or labeling on user interface.

- c. Explanation of device safety interlocks.
- d. Explanation of all disinfection cycle signals, cautions and warnings.
- e. Device operating procedures.
- f. Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.
- g. Procedures to follow in case of UV lamp malfunction or failure.
- h. Procedures for disposing of mercury-containing UV lamps, if applicable.
- i. Identification of specific equipment that is compatible with the UV radiation dose generated by the device and can safely undergo UV low-level disinfection in the chamber device.
- j. Description of the required preparation of equipment for disinfection in the UV chamber device.
- k. Identification of the specific microbes used in successful performance testing of the device.
- l. Validated instructions for cleaning and disinfection of the device.

CONCLUSION

The *de novo* for the Vioguard Self-Sanitizing Keyboard (Model UVKB50) is granted and the device is classified under the following:

Product Code: OSZ

Device/Product Name: Ultraviolet Radiation (UV) Chamber Disinfection Device

Class: II

Regulation: 21 CFR 880.6600