DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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August 3, 2015

Mr. J. David Egner
Director of Quality and Regulatory Compliance
Vioguard
401 Parkplace Center, Suite 200
Kirkland, Washington 98033

Re: DEN100013
Vioguard Self-Sanitizing Keyboard (Model UVKB50)
Evaluation of Automatic Class III Designation – *De Novo* Request
Regulation Number: 880.6600
Regulation Name: Ultraviolet Radiation (UV) Chamber Disinfection Device
Regulatory Classification: Class II
Product Code: OSZ
Dated: November 2, 2010
Received: November 4, 2010

Dear Mr. Egner:

This letter corrects our classification order of December 20, 2011.

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 Vioguard Self-Sanitizing Keyboard (Model UVKB50), an over-the-counter device under 21 CFR Subpart C that is indicated:

> *For use in a healthcare environment to reduce microbial populations typically found on a computer keyboard*.

> ***Device Effectiveness***
> *In laboratory testing, the Vioguard Self-Sanitizing Keyboard (Model UVKB50) 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*

FDA concludes that this device should be classified into class II. This order, therefore, classifies the Vioguard Self-Sanitizing Keyboard (Model UVKB50), and substantially equivalent devices of this generic type, into class II under the generic name, Ultraviolet radiation (UV) Chamber Disinfection Device.

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.

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 new 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, within 30 days of receiving notice of the NSE determination, request FDA to make a risk-based classification of the device under section 513(a)(1) of the Act. 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** classifying the device type.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on October 28, 2010 automatically classifying the Vioguard Self-Sanitizing Keyboard (Model UVKB50) in class III, because it was not within a type of device which was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, nor which was subsequently reclassified into class I or class II. On November 4, 2010, FDA received your *de novo* requesting classification of the Vioguard Self-Sanitizing Keyboard (Model UVKB50) into class II. The request was submitted under section 513(f)(2) of the FD&C Act. In order to classify the Vioguard Self-Sanitizing Keyboard (Model UVKB50) 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 the Vioguard Self-Sanitizing Keyboard (Model UVKB50) indicated for use *in a healthcare environment to reduce microbial populations typically found on a computer keyboard* 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 Table 1.

Table 1 – Identified Risks to Health and Mitigation Measures

Identified Risks	**Mitigation Measures**
Inadequate Equipment Disinfection	Performance Testing Labeling
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

In combination with the general controls of the FD&C 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 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.

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 radiation (UV) Chamber Disinfection Device they intend to market prior to marketing the device and receive clearance to market from FDA.

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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the FD & C Act); 21 CFR 1000-1050.

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.

If you have any questions concerning this classification order, please Elizabeth Claverie at (301)-796-6298.

Sincerely yours,

Jonette R. Foy -S

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