

Evaluation Report for Category B, Subcategory 3.12 Application

Application Number: 2023-4566
Application: Changes to Product Labels - New Site or Host
Applicant: Aerohygenx Incorporated
Product: Aero HygenX RAY - Autonomous UVC Robot
Registration Number: 34541
Active ingredient (a.i.): Device generating ultraviolet C (wavelength 100-280 nm)
PMRA Document Number: 3627940

Purpose of Application

The purpose of this application was to revise the use claims for the commercial antimicrobial device, Aero HygenX RAY – Autonomous UVC Robot. The label is being amended to remove aircraft use, and instead to add the use in hospitals, healthcare and non-healthcare commercial and public buildings.

Health Assessments

Potential sites of exposure to UVC radiation are ocular and dermal. The main acute skin lesion from exposure to ultraviolet radiation (UVR) is erythema or sunburn. Erythema can be induced by ultraviolet light (including UVC) and the wavelength of light, skin type, and skin pigmentation all influence whether it will occur. Other acute skin responses to ultraviolet light include tanning and photosensitivity. Damage to skin cells can increase the rate of aging of the skin or cause skin cancer. The principal acute effects of UVR on the eye are photokeratitis (inflammation of the cornea) and photoconjunctivitis (inflammation of the conjunctiva). The most important cellular target for UVR is DNA which has an absorption peak in the UVC spectrum at 260 nm. It is generally accepted that UVC radiation is a cause of carcinogenicity in mammals. Chronic UVR exposure is believed to be at least one of the causative factors in the development of cataracts.

The risks to users and bystanders are acceptable when Aero HygenX RAY - Autonomous Robot is used in hospitals, healthcare and non-healthcare commercial and public buildings according to label directions. Precautionary and direction for use statements on the product label aimed at mitigating user, bystander and residential exposure are considered adequate to protect individuals from any potential risk due to exposure.

Chemistry and Environmental Assessments

Chemistry and environmental assessments were not required for this application.

Value Assessment

The conventional practice of manual cleaning and disinfection of high-touch surfaces benefits from additional supplemental sanitization. Aero HygenX RAY - Autonomous UVC Robot has demonstrated it can autonomously map and deliver UV-C light to exposed surfaces in a room at heights ranging from 0 to 250 cm, at doses capable of killing 99.9% of bacteria, and 99.99% of viruses. Aero HygenX RAY - Autonomous UVC Robot has acceptable value as an antimicrobial device, and will serve as a supplement to, but not a replacement for, conventional cleaning and disinfection products.

Conclusion

The Pest Management Regulatory Agency has completed an assessment of the information provided, and has found the information acceptable to support the amendment of the label for Aero HygenX RAY – Autonomous UVC Robot to remove aircraft use, and add use in hospitals, healthcare and non-healthcare commercial and public buildings.

References

PMRA Document Number	Reference
3612158	2024, Response to Deficiency Letter dated 8 July, 2024, DACO 10.2.3.3(E)
3616907	2024, Response to Additional Information Request dated 15 July 2024, DACO 10.2.3.3(E)
3616908	2024, Revised Movement Map, DACO 10.2.3.3
3616909	2024, Revised Spreadsheet, DACO 10.2.3.3
3497759	2023, Use Description Scenario, DACO: 5.2
3497760	2023, Device Specifications, DACO: 5.2
3497771	2023, Quick Start Guide, DACO: 5.2
3522169	2023, RAY - Device Specifications, DACO: 5.2
3497761	2021, UL Certificate, DACO: 10.6, 5.2

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