Questions on the U.S. Regulatory Coverage of UV Devices in a Hospital

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Decision Criteria	*Reference*
1. Does this device produce Ultraviolet radiation?	
1.1. EPA's Definition:	EPA Publication EPA 430-F-10-025, "UV Radiation" dtd, June 2010- (https://www.epa.gov/sites/production/files/documents/uvradiation.pdf)
1.1.1. UV radiation is classified into three types or bands—UVA, (wavelength: 320-400 nm), UVB (wavelength: 290-320 nm and UVC (wavelength: 100-290 nm)	
1.2. If "Yes," proceed to Question 2. Otherwise, thank you for your interest.	
2. Is it an EPA regulated disinfection device?	
2.1. Does the device fit EPA's definition?	EPA Regulation 40CFR152.500, PESTICIDE REGISTRATION AND CLASSIFICATION PROCEDURE, Requirements for devices" (https://www.ecfr.gov/cgi-bin/text-idx?SID=7302063a269d9db294e73ca3971a1e33&mc=true&node=se40.26.152_1500&rgn=div8)
2.1.1. "A device is defined as any instrument or contrivance (other than a firearm) intended for trapping, destroying, repelling, or mitigating any pest or any other form of plant or animal life…	
2.1.2. "(other than man and other than a bacterium, virus, or other microorganism on or in living man or living animals)…	
2.1.3. This includes mitigating "…, mold/mildew, bacteria and viruses."	EPA's "Pesticide Devices: A Guide for Consumers" (https://www.epa.gov/safepestcontrol/pesticide-devices-guide-consumers#9)
2.1.4. This excludes "… Medical instruments or machines used to kill pests in or on living humans or animals are regulated by the Food and Drug Administration."	
2.2. If "Yes," this is a regulated disinfection device, covered by FIFRA and EPA regulations. Go to Question #3	
2.3. If "No," skip to Question #8.	
3. Is the device's producing 'Establishment' registered and compliant with EPA requirements?	
Requirements include	
3.1. Establishment registration	EPA Regulations 40CFR167.20, "Establishments requiring registration" (https://www.ecfr.gov/cgi-bin/text-

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Decision Criteria	Reference
	idx?SID=2e83a1530ce4759d881e53a99f9352a6&mc=true&node=se40.26.167_120&rgn=div8)
3.1.1. Covers any establishments, inside or outside the US, where the device is produced	EPA Regulations 40CFR167.20(a)(1) and (3) – see website above
3.2. Establishment record keeping and reporting	EPA Regulation 40CFR167.85 "Recordkeeping and Reporting Requirements" (https://www.ecfr.gov/cgi-bin/retrieveECFR?gp=&SID=2e83a1530ce4759d881e53a99f9352a6&mc=true&n=pt40.26.167&r=PART&ty=HTML#se40.26.167_185)
3.3. Labeling for … [pesticide] devices	EPA Regulation 40CFR156.10 "Labeling requirements" (https://www.ecfr.gov/cgi-bin/text-idx?SID=10a101986c7fe136742396a6c0eed0f6&mc=true&node=se40.26.156_110&rgn=div8)
3.4. Requirements mandate that there be 'no false or misleading pesticidal claims'	EPA Regulation 156.10(a)(5) "False or misleading statements" (same as 40CFR156.10, above)
4. Is this UV disinfection device intended for 'whole room disinfection'?	
4.1. FDA's Definition for covered devices excludes:	FDA Regulation 21CFR880.6600(a), "Ultraviolet (UV) radiation chamber disinfection device - Identification" (https://www.ecfr.gov/cgi-bin/text-idx?SID=0e074ddfdd2725b1e9c6a3aa5fdc9791&mc=true&node=pt21.8.880&rgn=div5#se21.8.880_16600)
4.1.1."… self-contained open chamber UV radiation disinfection devices intended for whole room disinfection in a health care environment."	
4.2. If this definition fits, the device is regulated by EPA, not FDA; skip to Question #8.	
4.3. If it does not fit, it may be covered by FDA regulation; continue to Question #5	
5. Is the device a 'UV Disinfection chamber'?	
5.1. FDA's Definition	FDA Regulation 21CFR880.6600(a), "Ultraviolet (UV) radiation chamber disinfection device - Identification" (https://www.ecfr.gov/cgi-bin/text-idx?SID=0e074ddfdd2725b1e9c6a3aa5fdc9791&mc=true&node=pt21.8.880&rgn=div5#se21.8.880_16600)
5.1.1."An ultraviolet (UV) radiation chamber disinfection device is intended for the low-level surface disinfection of non-porous equipment surfaces by dose-controlled UV irradiation.	
5.1.2."This classification does not include self-contained open chamber UV radiation disinfection devices intended for	

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Decision Criteria	*Reference*
whole room disinfection in a health care environment." (see Q#4)	
5.2. If "Yes," it is a Class-II medical device, regulated by FDA; continue to Q#6.	
5.3. If "No," continue to Q#8	
6. Does the device meet FDA's requirements for Class-II medical device "special controls," which include the following?	
6.1. (1) Performance testing must demonstrate:	FDA Regulation 21CFR880.6600 (b)(1) "Ultraviolet (UV) radiation chamber disinfection device - Classification—Class II (special controls)" (https://www.ecfr.gov/cgi-bin/text-idx?SID=0e074ddfdd2725b1e9c6a3aa5fdc9791&mc=true&node=pt21.8.880&rgn=div5#se21.8.880_16600)
6.1.1. (i) The chamber's ability to control the UV radiation dose during operation.	
6.1.2. (ii) The chamber's disinfection performance through microbial challenge testing.	
6.1.3. (iii) Evidence that the equipment intended to be processed is UV compatible.	
6.1.4. (iv) Validation of the cleaning and disinfection procedures.	
6.1.5. (v) The ability of the device to continue to perform to all specification after cleaning and disinfection.	
6.1.6. (vi) Whether the device generates ozone (if so, 21 CFR 801.415, Maximum acceptable level of ozone, applies). (see Q#9)	
6.2. (2) Appropriate software verification, validation, and hazard analysis must be performed.	FDA Regulation 21CFR880.6600(b)(2) …
6.3. (3) Appropriate analysis and/or testing must validate electrical safety, mechanical safety, and electromagnetic compatibility of the device in its intended use environment.	FDA Regulation 21CFR880.6600(b)(3) …
6.4. (4) The labeling must include:	FDA Regulation 21CFR880.6600(b)(4) …
6.4.1. (i) UV hazard warning labels.	
6.4.2. (ii) Explanation of all displays and/or labeling on user interface.	
6.4.3. (iii) Explanation of device safety interlocks.	
6.4.4. (iv) Explanation of all disinfection cycle signals, cautions and warnings.	

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Decision Criteria	*Reference*
6.4.5. (v) Device operating procedures.	
6.4.6. (vi) Identification of the expected UV lamp operational life and instructions for procedures on replacement of the UV lamp when needed.	
6.4.7. (vii) Procedures to follow in case of UV lamp malfunction or failure.	
6.4.8. (viii) Procedures for disposing of mercury-containing UV lamps, if applicable.	
6.4.9. (ix) Identification of specific equipment that is compatible with the UV radiation dose generated by the device and that can safely undergo UV radiation low-level disinfection in the chamber device.	FDA Regulation 21CFR880.6600(b)(4) …
6.4.10. (x) Description of the required preparation of equipment for disinfection in the UV radiation chamber device.	
6.4.11. (xi) Identification of the specific microbes used in successful performance testing of the device.	
6.4.12. (xii) Validated instructions for cleaning and disinfection of the device.	
6.5. Continue to Q#8	
7. Is the device a "Medical ultraviolet air purifier"?	
7.1. FDA's Definition:	FDA Regulation 21CFR880.6500 "Medical ultraviolet air purifier" (https://www.ecfr.gov/cgi-bin/text-idx?SID=0e074ddfdd2725b1e9c6a3aa5fdc9791&mc=true&node=pt21.8.880&rgn=div5#se21.8.880_16600)
7.1.1. "A medical ultraviolet air purifier is a device intended for medical purposes that is used to destroy bacteria in the air by exposure to ultraviolet radiation."	
7.2. If "Yes," does the device meet FDA's Class-II medical device "performance standards" requirements?	FDA Regulation 21CFR880.6500 (b)
7.3. Continue to Question #8	
8. Does the Manufacturer state that the device complies with existing safety standards?	
8.1. Assuming EPA Definition, cited in Q#1, applies, what are the safety standards cited? Some examples include	EPA Publication EPA 430-F-10-025, "UV Radiation" dtd, June 2010- (https://www.epa.gov/sites/production/files/documents/uvradiation.pdf)

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Decision Criteria	*Reference*
8.1.1. Per a 2003 memo, OSHA has no stated employee exposure limits for UV radiation	Memo, OSHA to Bolton, dtd Feb 26, 2003 (https://www.osha.gov/laws-regs/standardinterpretations/2003-02-26)
8.1.1.1. OSHA does provide limited guidance on UV its laser safety technical guidance	OSHA Technical Manual, Section III, Chapter 6, Part II. – "Nonbeam Optical Radiation Hazards" (https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_6.html)
8.1.1.1.1. "Ultraviolet radiation emitted from laser discharge tubes, pumping lamps and laser welding plasmas shall be suitably shielded to reduce exposure to levels below the ANSI Z 136.1 (extended source), OSHA PEL's, and/or ACGIH TLV's"	OSHA Technical Manual, Section III, Chapter 6, Part II.C – "Nonbeam Optical Radiation Hazards" (https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_6.html)
8.1.1.1.2. "…photochemical reactions are the principal cause of threshold level tissue damage following exposures to either actinic ultraviolet radiation (0.200 µm-0.315 µm) for any exposure time or "blue light" visible radiation (0.400 µm-0.550 µm) when exposures are greater than 10 seconds."	OSHA Technical Manual, Section III, Chapter 6, Part Iii.C.1 – "Biological Effects… - Other" (https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_6.html)
8.1.1.1.3. "Exposure in the UV-B range is most injurious to skin. In addition to thermal injury caused by ultraviolet energy, there is the possibility of radiation carcinogenesis from UV-B (0.280 mm - 0.315 mm) either directly on DNA or from effects on potential carcinogenic intracellular viruses."	OSHA Technical Manual, Section III, Chapter 6, Part Iii.C.3 – "Biological Effects… - Other" (https://www.osha.gov/dts/osta/otm/otm_iii/otm_iii_6.html)
8.1.1.2. The memo cites ANSI Z-136.1 on Laser Safety, which does contain two figures related to MPE for Ultraviolet Radiation – Figures 5 & 6	ANSI Standard for Safe Use of Lasers, ANSI Z136.1-2014 (https://assets.lia.org/s3fs-public/pdf/ansi-standards/samples/ANSI%20Z136.1_sample.pdf)
8.1.1.3. The memo also cites the American Conference of Governmental Industrial Hygienists (ACGIH)which produces an annual document "Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices."	ACGIH" Threshold Limit Values for Chemical Substances and Physical Agents & Biological Exposure Indices." (https://www.nsc.org/Portals/0/Documents/facultyportal/Documents/fih-6e-appendix-b.pdf)
8.1.2. There is a European Standard (EN 62471, aka IEC 62471) which covers UV exposure limits, and specifically includes datasheets identifying cataract and skin erythema risks	European Standard, EN 62471 "Photobiological safety of lamps and lamp systems" (http://tbt.testrust.com/image/zt/123/100123_2.pdf)

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Decision Criteria	*Reference*
9. Does the device produce Ozone?	
9.1. FDA Definition	
9.1.1. "(a) Ozone is a toxic gas with no known useful medical application in specific, adjunctive, or preventive therapy. In order for ozone to be effective as a germicide, it must be present in a concentration far greater than that which can be safely tolerated by man and animals."	FDA Regulation 21 CFR 801.415 "Maximum acceptable level of ozone," sub-para. (a) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?fr=801.415)
9.2. If "Yes," does operation of the device in accordance with the manufacturer's guidance result in ozone levels that comply with 21CFR801.415(c)?	FDA Regulation 21 CFR 801.415 "Maximum acceptable level of ozone," sub-para. (c) (https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?fr=801.415)