Product Classification

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Device	Disinfector, Medical Devices
Regulation Medical Specialty	General Hospital
Review Panel	General Hospital
Product Code	MEC
Premarket Review	Surgical and Infection Control Devices[6] (OHT4) Infection Control and Plastic Surgery Devices (DHT4B)
Submission Type	510(K) Exempt
Regulation Number	880.6992
Device Class	2
Total Product Life Cycle (TPLC)	TPLC Product Code Report[7]
GMP Exempt?	No
Summary Malfunction Reporting	Ineligible

Note: Class II devices the Food and Drug Administration (FDA) has also published a list of class II (special controls) devices[8] subject to certain limitations, that are exempt from premarket notification requirements under the Food and Drug Administration Modernization Act of 1997 (FDAMA) and the 21st Century Cures Act of 2016 (Cures Act). FDA believes that these exemptions will relieve manufacturers from the need to submit premarket notification submissions for these devices and will enable FDA to redirect the resources that would be spent on reviewing such submissions to more significant public health issues. FDA is taking this action in order to meet requirements of FDAMA and the Cures Act.

Implanted Device?	No
Life-Sustain/Support Device?	No

Recognized Consensus Standard

- 19-42 IEC 61326-1 Edition 3.0 2020-10
  Electrical equipment for measurement, control and laboratory use - EMC requirements - Part 1: General requirements[9]

Third Party Review	Not Third Party Eligible

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Page Last Updated: 11/21/2022

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