



Bluezone Model 450 Air Cleaner Receives FDA 510(k) Class II Medical Device Clearance

WOBURN, MA. – February 22, 2022–Bluezone Products, Inc., a Massachusetts manufacturer of germicidal UV-C based air cleaning products, announced today that the U.S. Food and Drug Administration (FDA) cleared its Bluezone Model 450 air cleaner as a Class II medical device. The Bluezone Model 450 Air Purifier is a free standing, air purifying device utilizing ultraviolet light for the inactivation of viral aerosols in medical facilities and occupied spaces. With this clearance, the Bluezone Model 450 will now be offered as a medical device to hospitals, nursing homes, and medical and dental offices to mitigate risks associated with the coronavirus.

The FDA clearance was contingent on the extensive amount of testing conducted by Bluezone Products Inc. to quantify the high-level performance of the Bluezone Model 450 in killing airborne viruses, bacteria and mold. Independent third-party testing in large, room-sized chambers demonstrated that the Model 450 achieved a 99.9995% kill of MS2 Bacteriophage, an accepted SARS-CoV-2 surrogate, as well as a 99.99% kill of mold and bacterial spores. In addition, to achieve this clearance, Bluezone Products, Inc. needed to demonstrate that the Model 450 met stringent safety standards.

“We are very pleased to have successfully completed the 510(k) clearance process and to now offer a medical device to reduce viral load in the air,” said Karen Benedek, CEO of Bluezone Products Inc. “There are few options to decrease the risk associated with airborne viruses that do not create some discomfort and discord. Air cleaning with germicidal UV-C is a proven, effective virus reduction method for all occupied spaces. The process of FDA clearance is exhaustive, and we are very pleased that the Model 450 has achieved this milestone.”

The decision of Bluezone management to pursue and secure a Class II medical device clearance reflects the company’s commitment to produce only scientifically proven products. Currently available in the marketplace are the Bluezone highly effective, quiet, high-capacity air cleaners for K-12 schools, higher education, daycares, and office spaces.

Bluezone Products, Inc. partners with The Middleby Corporation to provide air cleaning products to restaurants and the food industry. Middleby is a world leader in innovative equipment solutions and is committed to offering advanced products that make the indoor spaces safer for customers and employees.

“The FDA clearance is important today, especially as mask mandates are ending and we all strive to maintain layers of virus protection in indoor spaces. Effectively and safely cleaning the indoor air at senior living sites and medical locations as well as restaurants could not be a more urgent.” said Scott Heim, Middleby Division President. leading the Bluezone-by-Middleby effort.

“UV-C light technology is already recognized as the gold standard for air cleaning and virus destruction. The FDA clearance provides further confirmation of the safety and efficacy of the Bluezone air cleaners in any indoor application,” Heim continued.

The Bluezone Model 450 air cleaners are immediately available at www.bluezone.com



ABOUT BLUEZONE PRODUCTS, INC.

Bluezone Products, Inc. is dedicated to helping people safely get back to work, school and recreation during the Covid-19 pandemic. We proudly create scientifically tested air purifiers that offer safety and fresh preservation solutions to our customers. Bluezone Products, Inc. is reinventing the science of fresh air. By applying our U.S. military-developed technology, Bluezone Products, Inc. creates clean and healthy spaces to live and work, grow crops, and store food. Our products for occupied spaces reduce the risk of spreading airborne viruses inside buildings. Our wide range of commercial and custom products keep every link of the global perishable supply chain Bluezone-fresh for maximum product quality, employee health, and financial return.

ABOUT THE MIDDLEBY CORPORATION

The Middleby Corporation is a global leader in the foodservice equipment industry. The company develops, manufactures, markets and services a broad line of equipment used in the commercial foodservice, food processing, and residential kitchen equipment industries. For more information about The Middleby Corporation and the Bluezone by Middleby brand, please visit www.middleby.com and www.bluezone.com