

United States of America
FEDERAL TRADE COMMISSION
Washington, D.C. 20580

Division of Advertising Practices

April 7, 2020

Via Electronic Mail (lbrett@bbbnp.org)

Laura Brett, Esq.

Vice President

National Advertising Division

112 Madison Avenue, 3rd Floor

New York, NY 10016

Re: Advertising by 3B Medical, Inc. for Lumin CPAP Cleaner

Dear Ms. Brett:

Thank you for your letter referring a NAD decision regarding advertising by 3B Medical, Inc. ("3B") for its Lumin Continuous Positive Airway Pressure ("CPAP") Cleaner. A CPAP is a type of ventilator that helps people who have obstructive sleep apnea, a health condition that causes brief pauses in breathing during sleep. 3B's cleaner purportedly uses ultraviolet light to disinfect a CPAP device and its accessories. The NAD decision involves a challenge filed by 3B's competitor, SoClean, Inc., whose cleaning device purportedly uses ozone gas for disinfection. Your referral indicates that 3B has decided to comply with NAD's recommendations to discontinue unsubstantiated safety claims about SoClean's CPAP ozone-based cleaner.

In addition to reviewing the NAD case record, we consulted with staff of the Food and Drug Administration's Center for Devices and Radiological Health, which regulates CPAP devices and cleaners as medical devices. On February 27, 2020, the FDA issued a safety communication about the potential health risks of products that allegedly use ozone gas or ultraviolet light to clean, disinfect, or sanitize CPAP devices and accessories. According to the communication, FDA's laboratory tests found potential safety hazards with both types of devices and is working with manufacturers to submit the recommendations to support use of these

¹ U.S. Food & Drug Admin., Safety Communication: Potential Risks Associated With the Use of Ozone and Ultraviolet (UV) Light Products for Cleaning CPAP Machines and Accessories (Feb. 27, 2020), <https://www.fda.gov/medical-devices/safety-communications/potential-risks-associated-use-ozone-and-ultraviolet-uv-light-products-cleaning-cpap-machines-and> (last visited Apr. 7, 2020).

