



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

Division of Advertising Practices

April 7, 2020

Via Electronic Mail (lbrett@bbbn.org)

Laura Brett, Esq.  
Vice President  
National Advertising Division  
112 Madison Avenue, 3<sup>rd</sup> Floor  
New York, NY 10016

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

Dear Ms. Brett:

Thank you for your letter referring an 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 declined 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.<sup>1</sup> 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 recommended testing to support use of these

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<sup>1</sup> 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).

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devices as claimed. The FDA simultaneously issued a consumer alert<sup>2</sup> and an informational YouTube video<sup>3</sup> about CPAP cleaning devices.

In deference to FDA's expertise about the safety of CPAP cleaners, as well as that agency's current and anticipated regulatory actions, we have determined not to take additional action at this time. The Commission reserves the right to take such further action as the public interest may require. We appreciate your referral and the opportunity to continue supporting the NAD self-regulatory process.

Very truly yours,

*s/ Carolyn L. Hann*

Carolyn L. Hann  
Chief of Staff for Advertising Practices

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<sup>2</sup> U.S. Food & Drug Admin., Consumer Update: Continuous Positive Airway Pressure (CPAP) Machine Cleaning, <https://www.fda.gov/consumers/consumer-updates/continuous-positive-airway-pressure-cpap-machine-cleaning> (last visited Apr. 7, 2020).

<sup>3</sup> U.S. Food & Drug Admin., Watch This Before You Consider Using Ozone Gas or UV Light CPAP Cleaning Devices (Feb. 27, 2020), <https://www.youtube.com/watch?v=K9Bb7MzvVuM&feature=youtu.be> (last visited Apr. 7, 2020).