Re: Compliance of Castle Grade, LLC

To Whom It May Concern:

My name is Marc C. Sanchez, a food and drug attorney in private practice ("Counsel"). At the request of my client Castle Grade, LLC ("Company"), I am qualified to make the following written opinion. I am attorney in good standing with 10-years experience in FDA regulatory law, including extensive experience with medical device regulations. I also lecture on regulatory law subjects at Northeastern University and have published books, articles and interviews on several regulatory topics.

Company engaged my firm to act as regulatory counsel. As regulatory counsel, I have reviewed the Castle Grade G-Series Reusable N95 Protective Mask with Replaceable Filters ("G-Series N95 Masks"). The G-Series N95 Masks is a reusable N95 respirator with replaceable filters intended to fully cover the nose and mouth of the wearer to help reduce wearer exposure to pathogenic biological particulate. There are no unfiltered vents or openings. The area in the front of the G-Series N95 Masks is filtered and performance testing by Nelson Laboratories confirms the filtration meets NIOSH standards. The filtration works both ways, filtering air breathed out and air breathed in, making it safer for the wearer and those around them.

The G-Series N95 Masks currently comply with Section V of FDA’s Enforcement Policy for Face Masks and Respirators During the Coronavirus Disease (COVID-19) Public Health Emergency (Revised) Guidance for Industry and Food and Drug Administration Staff ("Enforcement Policy"). The G-Series N95 Masks are properly registered, labeled, and marketed under FDA’s Enforcement Policy.

1 Available at: https://www.fda.gov/media/136449/download
The G-Series N95 Masks meet and exceed the current CDC guidance to, “[w]ear a mask to keep your nose and mouth covered when in public settings…” including airports and airplanes.² The G-Series N95 Masks meet and exceed the current advisories from major airlines, such as those issued by United,³ Delta,⁴ and American Airlines.⁵ There is no requirement for cloth masks or surgical masks.

Therefore, for these reasons, namely G-Series N95 Masks fully covers the nose and mouth, there are no openings or vents, and the use of NIOSH level N95 filtration, I consider the Company compliant with the Food Drug & Cosmetic Act, the Public Health Services Act, and CDC travel recommendations.

Kind Regards,

Marc C. Sanchez, Esq.
Regulatory Counsel
Castle Grade, LLC

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³ “For everyone’s safety, all travelers are required to wear a face covering with no vents or openings that fully covers their nose and mouth. Face coverings must be worn during the entire flight, unless travelers are eating or drinking.” (Available at: https://www.united.com/ual/en/us/fly/travel/notices.html).

⁴ “Delta remains committed to protecting the well-being of our customers and employees by requiring all customers and employees to wear a mask or face covering across all Delta touchpoints.” (Available at: https://www.delta.com/us/en/travel-update-center/overview)

⁵ “A face covering can be a mask or any secured cloth that covers your nose and mouth and fits snugly under the chin.” (Available at: https://www.aa.com/i18n/travel-info/coronavirus-updates.jsp).