WARNING LETTER

King Systems Corp. dba Ambu, Inc.

MARCS-CMS 661617 — AUGUST 16, 2023

Delivery Method:

VIA UNITED PARCEL SERVICE

Product:

Medical Devices

Recipient:

Steven Block

President & CEO

King Systems Corp. dba Ambu, Inc.

6721 Columbia Gateway Drive, Suite 200
Columbia, MD 21046
United States

Issuing Office:

Center for Devices and Radiological Health

United States

WARNING LETTER
CMS# 661617

August 16, 2023

Dear Mr. Block:

During an inspection of your firm, King Systems Corp., dba Ambu, Inc., located at 15011 Herriman Blvd, Noblesville, IN 46060 on two days from May 15, 2023 through May 16, 2023, investigators from the United States Food and Drug Administration (FDA) determined that your
firm is a manufacturer of the King LTS-D branded supraglottic airway with gastric access lumen. Under section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 321(h), this product is a device because they are intended for use in the diagnosis of disease or other conditions or in the cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body.

Our inspection also revealed that the King LTS-D branded supraglottic airway with gastric access lumen is adulterated under section 501(f)(1)(B) of the Act, 21 U.S.C. § 351(f)(1)(B), because your firm does not have an approved application for premarket approval (PMA) in effect pursuant to section 515(a) of the Act, 21 U.S.C. § 360e(a), or an approved application for an investigational device exemption under section 520(g) of the Act, 21 U.S.C. § 360j(g).

The device is also misbranded under section 502(o) the Act, 21 U.S.C. § 352(o), because your firm did not notify the agency of its intent to introduce the device into commercial distribution, as required by section 510(k) of the Act, 21 U.S.C. § 360(k). For a device requiring premarket approval, the notification required by section 510(k) is deemed satisfied when a PMA is pending before the agency. [21 CFR 807.81(b)] The kind of information that your firm needs to submit in order to obtain approval or clearance for the device is described on the Internet at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm. The FDA will evaluate the information that your firm submits and decide whether the product may be legally marketed.

Statements on your website (https://www.ambuusa.com/airway-management-andanaesthesia/laryngeal-tubes/product/ambu-king-lts-d-disposable-laryngeal-tube) promote the device with an intended use for pediatric populations weighing less than 5 kg, 5-12kg, 12-25kg, and 25-35 kg. However, the cleared indication for use for your device is for adult patients (K033189.pdf (fda.gov); K033186.pdf (fda.gov); K021634.pdf (fda.gov), and not for pediatric sizes. Use of this device in a pediatric population raise different questions of safety and effectiveness that may lead to patient adverse events. Therefore, please remove these unsupported performance claims from your website, or please provide a 510(k) with this proposed indication for use. For additional information, please refer to the following guidance: Deciding When to Submit a 510(k) for a Change to an Existing Device - Guidance for Industry and Food and Drug Administration Staff (fda.gov).

Your firm should take prompt action to address any violations identified in this letter. Failure to adequately address this matter may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, seizure, injunction, and civil money penalties.

Other federal agencies may take your compliance with the FD&C Act and its implementing regulations into account when considering the award of federal contracts.

Please notify this office in writing within fifteen business days from the date you receive this letter of the specific steps your firm has taken to address the noted violations, as well as an explanation of how your firm plans to prevent these violations, or similar violations, from occurring again. Include documentation of the corrections and/or corrective actions (which must address systemic problems) that your firm has taken. If your firm's planned corrections and/or corrective actions will occur over time, please include a timetable for implementation of those activities. If corrections and/or corrective actions cannot be completed within fifteen business days, state the reason for the delay and the time within which these activities will be completed. Your firm's response should be comprehensive and address any violations included in this Warning Letter. If you believe that your products are not in violation of the FD&C Act, include your reasoning and any supporting information for our consideration as part of your response.

Your firm's response should be sent to: Gina Brackett, Director of Compliance Branch, at oradevices1firmresponse@fda.hhs.gov. **Refer to CMS # 661617** when replying. If you have any questions about the contents of this letter, please contact: Sean Moynihan, Compliance Officer, at 410-779-5134 or sean.moynihan@fda.hhs.gov.

Finally, you should know that this letter is not intended to be an all-inclusive list of the violations at your firm's facility. It is your firm's responsibility to ensure compliance with applicable laws and regulations administered by FDA. The specific violations noted in this letter and in the Inspectional Observations, FDA 483, issued at the close of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality management systems. Your firm should investigate and determine the causes of any violations and take prompt actions to address any violations and bring the products into compliance.

Sincerely,
/S/

Dr. Malvina Eydelman
Director
OHT 1: Office of Ophthalmic, Anesthesia, Respiratory,
ENT & Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

/S/

Joseph Matrisciano, Jr.
Program Division Director
Office of Medical Device and Radiological Health
Operations, Division 1 - East

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