May 1, 2022

Airway Shield, S.L.
℅ Ellie Reynolds
Regualtory Affairs Consultant
Proxima Clinical Research
2450 Holcombe Boulevard
Houston, Texas 77021

Re: Q220427
Trade/Device Name: Airway Shield Medical Device
Received: March 2, 2022

Dear Ellie Reynolds:

The Food and Drug Administration (FDA) has received the above submission requesting entrance into the Safer Technologies Program ("STeP"). The proposed indications for use is: "Airway Shield is intended to be used by anesthesiologists in hospital operating rooms to facilitate endotracheal intubation, allowing the anesthesiologist to direct the tube into the trachea. Airway Shield is intended to reduce the spread of aerosols and droplets emitted by the patient to medical staff." We are pleased to inform you that your device meets the eligibility factors and has been included in STeP for your proposed indications. Please refer to the FDA guidance document entitled "Safer Technologies Program for Medical Devices" for more information regarding the program, available at https://www.fda.gov/media/130815/download.

Information on the available mechanisms for obtaining feedback from the Agency on device development for devices in STeP is available in the FDA guidance document for STeP referenced above. Sponsors of devices included in STeP also have the option to request feedback from FDA through mechanisms that are available for devices, generally. These mechanisms are described in the FDA guidance document entitled "Requests for Feedback and Meetings for Medical Device Submissions: The Q-Submission Program", available at https://www.fda.gov/media/114034/download. When submitting any new requests for feedback, please reference Q220427. Any new submission or Q-Sub amendment must be provided as an eCopy. For more information about FDA's eCopy program, including the technical standards for an eCopy, refer to the guidance document, "eCopy Program for Medical Device Submissions" at https://www.fda.gov/media/83522/download. In addition, we strongly encourage you to visit FDA's eSubmitter website at https://www.fda.gov/industry/fda-esubmitter/cdrh-esubmitter-program for assistance developing an eCopy consistent with the technical standards prior to sending a submission to FDA.

The submission should include the FDA reference number for this Q-Sub , and should be submitted to the following address:

U.S. Food and Drug Administration
Center for Devices and Radiological Health (CDRH)
IDE Document Control Center - WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

You are reminded that inclusion in STeP does not change the requirements for approval of an application for an Investigational Device Exemption (IDE) under section 520(g) or marketing authorizations under section 515(c), 510(k), or 513(f)(2) of the Federal Food, Drug, and Cosmetic Act. Additionally, clinical data submitted to support any marketing submission for your device should constitute valid scientific evidence (21 CFR 860.7). You are further advised that inclusion in STeP does not guarantee approval of a future IDE application or supplement or that a future marketing submission will ultimately be approved, cleared, or granted.

If you have any questions, please contact Benjamin Sommerkorn at Benjamin.Sommerkorn@fda.hhs.gov.

Sincerely,

James J. Lee -S

James J. Lee, Ph.D.
Director
DHT1C: Division of Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health