U.S. FOOD & DRUG ADMINISTRATION

May 5, 2020

Judy P. Ways, Ph.D.
Vice President, Regulatory Affairs
Lungpacer Medical USA, Inc.
260 Sierra Drive, Suite 116
Exton, PA 19341

Re: EUA 200178
Trade/Device Name: Lungpacer Diaphragm Pacing Therapy System
EUA Issued: April 14, 2020
Request for Amendments Received: April 20, 2020

Dear Dr. Ways:

This is to notify you that your request to amend the authorized labeling for your Emergency Use Authorization has been granted. The changes requested in the Fact Sheets for Healthcare Providers (HCP) and Patients include the following: 1) clarification regarding limitation of treatment duration and use of product in patients requiring invasive mechanical ventilation to ensure consistency with Letter of Authorization, 2) edit to reflect potential use of the product on spontaneously breathing patients, 3) removal of the term, "implant" to accurately reflect use of the product, 4) addition of the word, "rare" for procedure-related deaths in the HCP Fact Sheet for consistency with the Patient Fact Sheet, and 5) addition of the word, "improvement" to describe the potential benefit of diaphragm muscle strength. The changes requested to the device's Instructions for Use have been: 1) inclusion of clarifications to the indications for use to ensure consistency with the Letter of Authorization, including limitation of treatment duration to 30 days, clarifying use of the product in patients on invasive mechanical ventilation and those who are at high risk for weaning failure; and 2) removal of the word *draft* from the Instructions for Use and the addition of the official issue date on the sponsor's developed Instruction for Use.

Upon review, we concur that the proposed changes to the Facts Sheets and Instructions for Use in EUA 200178 are supported. By submitting these amendments for review by FDA, you have complied with the Conditions of Authorization stated in the Letter of Authorization issued to Lungpacer Medical USA, Inc. on April 14, 2020.

Sincerely,

/S/

Malvina Eydelman, M.D.
Director, Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration

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