June 30, 2020

CLEW Medical, Ltd.
c/o Ms. Yarmela Pavlovic
Manatt, Phelps & Phillips, LLP
1 Embarcadero Center, 30th Floor
San Francisco, CA 94111

Re: EUA 200967
Trade/Device Name: CLEWICU System
EUA Issued: May 26, 2020
Request for Amendments Received: June 2, 2020

Dear Ms. Pavlovic:

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 Sheet for Healthcare Providers (HCP) were to update the two tables summarizing the analysis of Respiratory Failure and Hemodynamic Instability model performance to accurately reflect the corrections to validation testing discussed in your June 2, 2020 e-mail. The changes requested to the device's Instructions for Use were to update the four tables summarizing the analyses of Respiratory Failure and Hemodynamic Instability model performance (including decreased data availability) to accurately reflect the corrections to validation testing discussed in your June 2, 2020 e-mail.

Upon review, we concur that the proposed changes to the Facts Sheets and Instructions for Use in EUA 200967 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 CLEW Medical, Ltd. on May 26, 2020.

Sincerely,

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Bram Zuckerman, M.D.
Director, Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health
Food and Drug Administration