U.S. FOOD & DRUG ADMINISTRATION

April 21, 2020

Ms. Sunny Yi
Sr. Manager, Global Regulatory Processes
Philips Medizin Systeme Boeblingen GmbH
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Dear Ms. Yi:

This letter is in response to your[1] request that the Food and Drug Administration (FDA) issue an Emergency Use Authorization (EUA) for the Philips Medizin Systeme Boeblingen GmbH's IntelliVue Patient Monitors MX750/MX850,[2,3] IntelliVue 4-Slot Module Rack FMX-4,[4,5] and IntelliVue Active Displays AD75/AD85[6] (hereafter collectively referred to as "IntelliVue Patient Monitors"), intended to be used by healthcare professionals in the hospital environment for remote monitoring of adult, pediatric, and neonate patients having or suspected of having Coronavirus-2019 (COVID-19) to reduce healthcare provider exposure to COVID-19. The IntelliVue Patient Monitors are not intended for home use.

On February 4, 2020, pursuant to section 564(b)(1)(C) of the Federal Food, Drug, and Cosmetic Act (the Act), the Secretary of the Department of Health and Human Services (HHS) determined that there is a public health emergency that has a significant potential to affect national security

[1] For ease of reference, this letter will use the term "you" and related terms to refer to Philips Medizin Systeme Boeblingen GmbH.
[2] The IntelliVue Patient Monitors MX750 and MX850 are intended to be used for monitoring and recording of, and for generating alarms for, multiple physiological parameters of adult, pediatric, and neonate patients with COVID-19.
[3] The IntelliVue Patient Monitors MX750/MX850 are not cleared or approved for marketing in the United States. This device is a design iteration of the IntelliVue Patient Monitors MX700 and MX800, which are legally marketed in the United States. IntelliVue Patient Monitors MX700 was originally cleared under K110622 and modified with K113441, K120366, K150310, and K151531. IntelliVue Patient Monitors MX800 was originally cleared under the name MP75 in K100939, the monitor was renamed to MX800 in a letter to FDA on July 1, 2010, and the monitor was modified under K101449, K102562, K110522, K113441, K120366, K150310, and K161531.
[4] The IntelliVue 4-Slot Module Rack FMX-4 is intended to connect to four individual plug-in physiological measurement modules to the dedicated host patient monitors for patients with COVID-19.
[5] The IntelliVue 4-Slot Module Rack FMX-4 is not cleared or approved in the United States; it is a design iteration of the IntelliVue 4-Slot Module Rack FMS-4. The IntelliVue 4-Slot Module Rack FMS-4 was originally cleared under K110622 and modified under K113441, K120366, K150310, and K161531.
[6] The IntelliVue Active Displays AD75 and AD85 are intended to be used as an additional independent display for the connected Philips patient monitor and can be used to remotely view screens and operation of, and to provide visual and audible alarms generated by the connected Philips patient monitor for COVID-19 patients. They are not cleared or approved for marketing in the United States.

or the health and security of United States citizens living abroad, and that involves the virus that causes COVID-19.[7] Pursuant to section 564 of the Act, and on the basis of such determination, the Secretary of HHS then declared on March 24, 2020, that circumstances exist justifying the authorization of emergency use of medical devices, including alternative products used as medical devices, due to shortages during the COVID-19 outbreak, subject to the terms of any authorization issued under that section.[8]

There are no adequate FDA approved, licensed, or cleared devices with remote alarm operability for remote patient monitoring. Based on design verification and validation studies performed in accordance with applicable consensus standards, FDA has concluded that the IntelliVue Patient Monitors may be effective for remotely monitoring the physiological parameters of patients in hospitals thereby reducing the healthcare providers' risks of exposure during the COVID-19 pandemic.

Having concluded that the criteria for issuance of this authorization under section 564(c) of the Act are met, I am authorizing the emergency use of the IntelliVue Patient Monitors as described in the Scope of Authorization (Section II) and pursuant to the Conditions of Authorization (Section III) of this letter.

I. Criteria for Issuance of Authorization

I have concluded that the emergency use of the IntelliVue Patient Monitors, as described in the Scope of Authorization (Section II) of this letter, for the monitoring of COVID-19 patients meets the criteria for issuance of an authorization under section 564(c) of the Act, because I have concluded that:

1. SARS-CoV-2, the virus that causes COVID-19, can cause a serious or life-threatening disease or condition, including severe respiratory illness, to humans infected by this virus;

2. Based on the totality of scientific evidence available to FDA, it is reasonable to believe that the IntelliVue Patient Monitors may be effective in preventing COVID-19 exposure in healthcare providers, through use of remote patient monitoring, and that the known and potential benefits of such products, for such use, outweigh the known and potential risks of the IntelliVue Patient Monitors; and,

3. There is no adequate, approved, and available alternative to the emergency use of the IntelliVue Patient Monitors for the intended use.[9]

[7] U.S. Department of Health and Human Services, *Determination of a Public Health Emergency and Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*. 85 FR 7316 (February 7, 2020).
[8] U.S. Department of Health and Human Services, *Declaration that Circumstances Exist Justifying Authorizations Pursuant to Section 564(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 360bbb-3*, 85 FR 17335 (March 27, 2020).
[9] No other criteria of issuance have been prescribed by regulation under section 564(c)(4) of the Act.

II. Scope of Authorization

I have concluded, pursuant to section 564(d)(1) of the Act, that the scope of this authorization is limited to the use of the IntelliVue Patient Monitors by healthcare professionals in the hospital environment for remote monitoring of adult, pediatric, and neonate patients having or suspected of having COVID-19 to reduce healthcare provider exposure to COVID-19. The remote monitoring capabilities of the Philips IntelliVue Patient Monitors reduce the amount of contact by healthcare providers with patients during the COVID-19 pandemic who are in isolation rooms, thereby reducing the healthcare providers' risk of exposure to the virus.

The Authorized Product: IntelliVue Patient Monitors

The IntelliVue Patient Monitors are intended for remote monitoring of the physiological parameters of patients in the hospital environment who have or are suspected of having COVID-19. Specifically, the IntelliVue Patient Monitors can be used to acquire multiple physiological patient signals including being able to remotely display measurement values, waves and trends, generate physiological and technical alarms, provide data recording, and support patient data management without requiring healthcare providers contact with the patient.

The IntelliVue Patient Monitor is comprised of the following components:

- IntelliVue Patient Monitors MX750/MX850
- IntelliVue 4-Slot Module Rack FMX-4
- IntelliVue Active Displays AD75/AD85
- Power Cord
- Mount

The IntelliVue Patient Monitors require the use of multiple commercial Plug-in Measurement Modules and Multi-Measurement Modules and Extensions marketed separately by Philips Medizin Systeme Boeblingen GmbH, as described in the authorized IntelliVue Patient Monitors Instructions for Use.

The IntelliVue Patient Monitors also require the use of additional accessories for physiological parameter measuring sensors commonly used in a hospital environment, as described in the authorized IntelliVue Patient Monitors Instructions for Use.

The above described IntelliVue Patient Monitors, when labeled consistently with the labeling authorized by FDA, the "Instructions for Use – IntelliVue Patient Monitor MX750/MX850," and "Instructions for Use Addendum – IntelliVue Active Displays AD75/AD85" (available at http://www.fda.gov/MedicalDevices/Safety/EmergencySituations/ucm161496.htm), together with the following product-specific information pertaining to emergency use, which is required to be made available to healthcare providers and patients, respectively:

- Fact Sheet for Healthcare Providers: Emergency Use of the Philips IntelliVue Patient Monitors MX750 And MX850, Philips Intellivue 4-Slot Module Rack FMX-4, and

Philips Intellivue Active Displays AD75 and AD85 During the COVID-19 Pandemic

- Fact Sheet for Patients: Emergency Use of the Philips Intellivue Patient Monitors MX750 And MX850, Philips Intellivue 4-Slot Module Rack FMX-4, and Philips Intellivue Active Displays AD75 and AD85 During the COVID-19 Pandemic

The above described product, when accompanied with the authorized labeling, is authorized to be distributed and administered under this EUA. This labeling may be revised by Philips Medizin Systeme Boeblingen GmbH in consultation with and with concurrence of the Division of Health Technology 2A/Office of Health Technology 2 /Office of Product Evaluation and Quality/Center for Devices and Radiological Health (DHT2A/OHT2/OPEQ/CDRH).

I have concluded, pursuant to section 564(d)(2) of the Act, that it is reasonable to believe that the known and potential benefits of the IntelliVue Patient Monitors in the specified population, when used for monitoring COVID-19 patients and used consistently with the Scope of Authorization of this letter (Section II), outweigh the known and potential risks of this product.

I have concluded, pursuant to section 564(d)(3) of the Act, based on the totality of scientific evidence available to FDA, that it is reasonable to believe that the authorized IntelliVue Patient Monitors may be effective in the monitoring of COVID-19 patients, when used consistently with the Scope of Authorization of this letter (Section II), pursuant to section 564(c)(2)(A) of the Act.

FDA has reviewed the scientific information available to FDA, including the information supporting the conclusions described in Section I above, and concludes that the authorized IntelliVue Patient Monitors, when used to monitor patients during the COVID-19 pandemic (as described in the Scope of Authorization of this letter (Section II)), meets the criteria set forth in section 564(c) of the Act concerning safety and potential effectiveness.

The emergency use of the IntelliVue Patient Monitors must be consistent with, and may not exceed, the terms of this letter, including the Scope of Authorization (Section II) and the Conditions of Authorization (Section III). Subject to the terms and conditions of this EUA and under the circumstances set forth in the Secretary of HHS's determination under Section 564(b)(1)(C) described above and the Secretary of HHS's corresponding declaration under section 564(b)(1), the IntelliVue Patient Monitors described above is authorized to monitor COVID-19 patients requiring monitoring of their physiological parameters.

This EUA will cease to be effective when the HHS declaration that circumstances exist to justify the EUA is terminated under section 564(b)(2) of the Act or when the EUA is revoked under section 564(g) of the Act.

III. Conditions of Authorization

Pursuant to section 564(e) of the Act, I am establishing the following conditions on this authorization:

Philips Medizin Systeme Boeblingen GmbH, as Sponsor of the Authorized Product

A. Philips Medizin Systeme Boeblingen GmbHmust comply with the labeling requirements under 21 CFR 801 Subpart A (general labeling provisions) and 21 CFR 801.109 (labeling for prescription devices), as well as those described in Section II of this letter, Scope of Authorization. As such, compliance with unique device identification regulations (see Subpart B of 21 CFR Part 801) is not required under this EUA.

B. Philips Medizin Systeme Boeblingen GmbH must comply with current good manufacturing practice requirements under section 360(f)(1) of the Act, including the quality system requirements under 21 CFR Part 820 with respect to the authorized IntelliVue Patient Monitors used in accordance with this EUA. Any deviations require review and concurrence from OHT2/OPEQ/CDRH.

C. Philips Medizin Systeme Boeblingen GmbH will make the IntelliVue Patient Monitors available with authorized labeling. Philips Medizin Systeme Boeblingen GmbH may request changes to the authorized labeling. Such changes require review and concurrence from DHT2A/OHT2/OPEQ/CDRH.

D. Philips Medizin Systeme Boeblingen GmbH may request changes to the Scope of Authorization (Section II in this letter) of the authorized IntelliVue Patient Monitors. Such requests will be made by Philips Medizin Systeme Boeblingen GmbH, in consultation with OHT2/OPEQ/CDRH, and require concurrence of, the Office of Counterterrorism and Emerging Threats (OCET)/Office of the Chief Scientist (OCS)/Office of the Commissioner (OC) and OHT2/OPEQ/CDRH.

E. Philips Medizin Systeme Boeblingen GmbH may request changes to any components or materials. Such requests will be made in consultation with and require concurrence of OHT2/OPEQ/CDRH.

F. Philips Medizin Systeme Boeblingen GmbH will have process in place for reporting adverse events of which they become aware to FDA under 21 CFR Part 803.

G. Philips Medizin Systeme Boeblingen GmbH will notify FDA of any authorized distributor(s)[10] of the authorized IntelliVue Patient Monitors including the name, address, and phone number of any authorized distributor(s) and provide authorized distributor(s) with a copy of this EUA and any updates.

Philips Medizin Systeme Boeblingen GmbH, and any Authorized Distributor(s)

H. Philips Medizin Systeme Boeblingen GmbH, and authorized distributors will distribute the authorized IntelliVue Patient Monitors with the authorized labeling only to healthcare facilities with healthcare providers who are adequately equipped, trained,

[10] "Authorized Distributor(s)" are identified by Philips Medizin Systeme Boeblingen GmbH in an EUA submission as an entity allowed to distribute the device.

and capable of using the IntelliVue Patient Monitors according to the criteria set forth by Philips Medizin Systeme Boeblingen GmbH.

I. Philips Medizin Systeme Boeblingen GmbH, and authorized distributors will make authorized labeling available on their websites.

J. Authorized distributors will make Philips Medizin Systeme Boeblingen GmbH aware of any adverse events of which they become aware.

K. Through a process of inventory control, Philips Medizin Systeme Boeblingen GmbH and authorized distributors will maintain records of the healthcare facilities to which they distribute the authorized IntelliVue Patient Monitors and the number of each product they distribute.

L. Philips Medizin Systeme Boeblingen GmbH and authorized distributor(s) are authorized to make available additional information relating to the emergency use of the authorized IntelliVue Patient Monitors that is consistent with, and does not exceed, the terms of this letter of authorization.

M. Philips Medizin Systeme Boeblingen GmbH and authorized distributor(s) will ensure that any records associated with this EUA are maintained until otherwise notified by FDA. Such records will be made available to FDA for inspection upon request.

Healthcare Facilities

N. Healthcare facilities using the authorized IntelliVue Patient Monitors must make available to patients the accompanying Patient Fact Sheet and make available to healthcare providers the accompanying Healthcare Provider Fact Sheet.

O. Healthcare facilities using the authorized IntelliVue Patient Monitors must make Philips Medizin Systeme Boeblingen GmbH aware of any adverse events.

P. Healthcare facilities will ensure healthcare providers using the authorized IntelliVue Patient Monitors are adequately equipped, trained, capable, and will maintain records of device usage.

Conditions Related to Advertising and Promotion

Q. All advertising and promotional descriptive printed matter relating to the use of the authorized IntelliVue Patient Monitors shall be consistent with the authorized labeling, as well as the terms set forth in this EUA and the applicable requirements set forth in the Act and FDA regulations.

R. No advertising or promotional descriptive printed matter relating to the use of the authorized IntelliVue Patient Monitors may represent or suggest that this product is safe or effective for the prevention or treatment of COVID-19.

S. All advertising and promotional descriptive printed matter relating to the use of the authorized IntelliVue Patient Monitors shall clearly and conspicuously state that:

- The IntelliVue Patient Monitors has neither been cleared or approved for the indication to assist in for monitoring and recording of, and for generating alarms for, multiple physiological parameters of adult, pediatric, and neonate patients having or suspected of having Coronavirus-2019 (COVID-19); and,

- The IntelliVue Patient Monitors has been authorized for the above emergency use by FDA under an EUA;

- The IntelliVue Patient Monitors have been authorized only for the duration of the declaration that circumstances exist justifying the authorization of the emergency use of medical devices under section 564(b)(1) of the Act, 21 U.S.C. § 360bbb-3(b)(1), unless the authorization is terminated or revoked sooner.

V. Duration of Authorization

This EUA will be effective until the declaration that circumstances exist justifying the authorization of the emergency use of medical devices is terminated under section 564(b)(2) of the Act or the EUA is revoked under section 564(g) of the Act.

Sincerely,

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RADM Denise M. Hinton
Chief Scientist
Food and Drug Administration

Enclosures