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Philips Respironics
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Monroeville, PA 15146

September 22, 2020

Division of Dockets Management
Department of Health and Human Services
Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Citizen Petition: Exemption from Medical Device Tracking Requirements

Dear Sir or Madam:

The undersigned submits this petition of behalf of Respironics, Inc. under Section 519(e) of the Federal Food, Drug, and Cosmetic Act ("FFDCA")[1] and 21 C.F.R. §§ 821.2 and 10.3 to request that the Food and Drug Administration ("FDA") issue an exemption from the device tracking requirements under 21 C.F.R. Part 821 for the Care Orchestrator Essence, cleared under the 510(k) pre-market notification K183226.

I. Action Requested

Respironics requests that FDA issue an exemption from the device tracking requirements under 21 C.F.R. Part 821 for the Care Orchestrator Essence. Respironics received a letter from FDA, signed October 28, 2019, to track this device.[2]

II. Statement of Grounds

We have set forth below the following required information, per 21 C.F.R. § 821.2(b):

- The name of the device, device class, and intended use(s);
- The reasons that compliance with the tracking requirements of this part is unnecessary;
- A complete description of alternative steps that are available; and
- Other information justifying the exemption.

A. Name of Device, Device Class, and Intended Use

The Care Orchestrator Essence is a software as a medical device ("SaMD") product intended to run as a desktop solution, and is sold only to healthcare professionals ("HCPs"). This SaMD is used and accessed only by HCPs – it is not used by or accessible to patients. This product is regulated by FDA as a Class II device and was

[1] 21 U.S.C. § 360i(e).

[2] *See* Tracking Order for Care Orchestrator Essence (K183226), at Attachment A.

cleared under the pre-market notification, K183226. Care Orchestrator Essence was cleared under the following product classification codes: BZD, MNS, MNT, CBK, and NOU. For the purposes of this petition, the term "Care Orchestrator Essence" includes all SaMD covered by K183226, including versions that may be marketed by Respironics using other trade names.

The cleared indications for use under K183226 are set forth below:

> Care Orchestrator Essence is intended for use by healthcare professionals (e.g., Physicians, Clinicians, Durable Medical Equipment providers) to gather, store, manage, and view compliance data for patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. The software also includes the ability to create new or updated prescriptions and/or performance settings, store them, and transmit them to compatible Respironics' non-life supporting therapy devices and Respironics Trilogy ventilator. Data and prescription settings are transferred between Care Orchestrator Essence and compatible devices via removable media. Care Orchestrator Essence is intended to be used in hospital, institutional, provider, and home care settings by healthcare representatives.
>
> The software does not perform automatic scoring or diagnosis. The data it provides are only one of several elements to consider when making decisions about patient therapy.[3]

The Care Orchestrator Essence labeling (help file) also includes the above Indications for Use statement.[4] In addition, the labeling states the following:

> Care Orchestrator Essence allows home care providers and physicians to manage patient information. The software provides a central data management system that tracks patient progress, collects and analyzes compliance and therapy data, and provides valuable reports about the data. The software can be downloaded from the Philips Software Portal using a registered username and password.[5]

B. Compliance with the Tracking Requirements Under Part 821 is Unnecessary for Care Orchestrator Essence

Section 519(e)(1) of the FFDCA states the following:

> (1) The Secretary may by order require a manufacturer to adopt a method of tracking a Class II or III device –

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3 *See* Attachments B and C (FDA clearance letter dated Oct. 18, 2019 and Indications for Use statement).

4 Attachment D (COE 3.0 Help File – 510k Submittal, at 1).

5 *Id.*

(A) the failure of which would be reasonably likely to have serious adverse health consequences; or

(B) which is –

(i) intended to be implanted in the human body for more than one year, or

(ii) a life sustaining or life supporting device used outside a device user facility.[6]

The Care Orchestrator Essence SaMD, however, does not meet the above requirements for a device tracking order. Care Orchestrator Essence is not intended to be implanted, nor is it a life sustaining or life supporting device.[7] Thus, subsections 519(e)(1)(B)(i) and (ii) of the FFDCA are not applicable.

Further, as described in more detail below, the failure of the Care Orchestrator Essence SaMD is not "reasonably likely to have serious adverse health consequences" under subsection 519(e)(1)(A).

1. The Intended Use of the Care Orchestrator Essence SaMD Is Limited and Unlikely to Result in Serious Adverse Health Consequences.

As noted above, Care Orchestrator Essence was cleared under K183226 for the following uses:

- By healthcare professionals to gather, store, manage, and view compliance data for patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices.
- To create new or updated prescriptions and/or performance settings, store them, and transmit them to compatible Respironics' non-life supporting therapy devices and Respironics Trilogy ventilator. Data and prescription settings are transferred between Care Orchestrator Essence and compatible devices via removable media.

The failure of the Care Orchestrator Essence SaMD to perform any of the above uses is not "reasonably likely to have serious adverse health consequences." The mere gathering, storage, management, and viewing of data from compatible therapy devices is generally recognized by FDA to be a low risk function. For example, FDA does not actively regulate software or systems that merely electronically receive, transfer, exchange, store, retrieve, convert formats, or display medical device data.[8]

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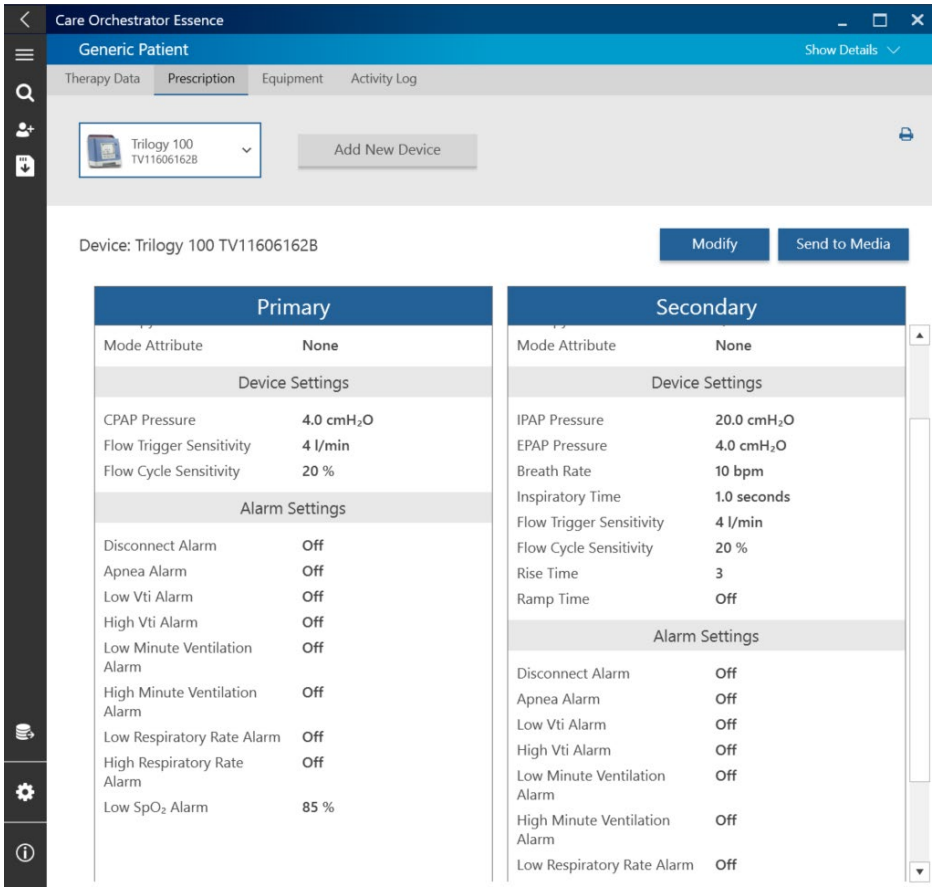
6 21 U.S.C. § 360i(e)(1).

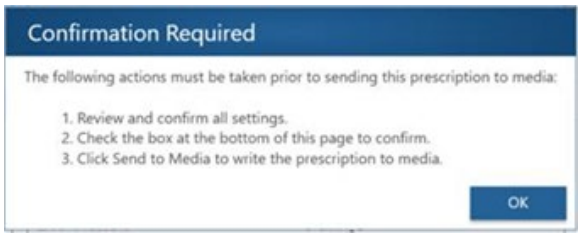
7 Although the Care Orchestrator Essence SaMD may be used independently in support of life-supporting devices, such as the Trilogy ventilator, the Care Orchestrator Essence SaMD itself is not life-supporting or life-sustaining, and is not intended for use outside of the HCP facility.

8 *See* FDA, Center for Devices & Radiological Health, Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices, Guidance for Industry and Food and Drug Administration Staff (Sept. 27. 2019), *available at* https://www.fda.gov/media/88572/download (last visited Apr. 17, 2020).

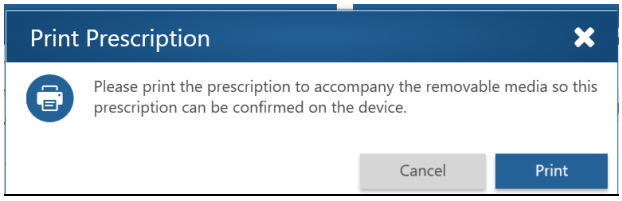
The ability to create new or updated prescriptions and/or performance settings, store them, and transmit them to compatible Respironics' non-life supporting therapy devices and the Respironics Trilogy ventilator also is unlikely to result in serious adverse health consequences. HCPs may use Care Orchestrator Essence to create or edit prescription/performance settings manually for all supported devices. Once the prescription is created and saved all prescriptions and settings are displayed to the HCP as shown below. Once saved, the HCP can choose to navigate away from the dialog, choose to make additional modifications or Send *the Settings* to Media.



When the HCP is prepared to send the new settings to SD Card for use with Trilogy, the SaMD requires an additional HCP review before the new settings can be written to the SD card – specifically, the SaMD will display the following message to the HCP when he/she chooses to Send to Media option.



In the prescription workflow for Trilogy, the HCP user must confirm the new settings displayed before the SaMD user can transfer the settings to the SD card. Once the prescription has been verified by the SaMD to have been correctly written to the media, the HCP is provided the option to Print the Prescription.



Additionally, for Trilogy ventilator prescriptions, the SaMD automatically erases any existing prescription data on the SD card prior to data transfer. Further, Trilogy prescriptions cannot be reused between devices – the prescription will be automatically removed from the SD card after the card is delivered to the device. Additionally, Trilogy verifies that the Device Serial Number on the media matches its own Device Serial Number. If it does not match, Trilogy will reject the update, and display information to the Trilogy user regarding the failed update.

In a typical use case, the HCP user then ships the SD card along with a printed Prescription to the patient and the patient or caregiver puts SD card into the relevant compatible device (a Respironics' non-life supporting therapy devices or the Respironics Trilogy ventilator).

For Trilogy, once the media is inserted into the device, the Trilogy prompts the patient or care giver with "Change Prescription?" on its user interface. The Trilogy then provides a method for the patient or care giver to view all of the new settings. Once all settings are shown, Trilogy displays OK. Once the OK is selected, the patient or care giver is notified that the Prescription change is complete. At this point patient setup and titration will continues With Trilogy and other supported non-life support ventilation, the patient or caregiver must confirm that he/she wants to install the update before the update will install.

Given the significant HCP involvement and oversight in generating any new or updated prescription/performance settings, the existing SaMD design controls in place for prescription validation and integrity checks for all supported devices, the caution statements generated by the SaMD before the HCP user completes any such change, the additional restrictions for Trilogy ventilators prescriptions, and the visibility of the change to the patient/caregiver, it is unlikely that this intended use would result in serious adverse health consequences.

2. The Risk Evaluation and Post Market Data for Care Orchestrator Essence SaMD Support that this Device is Unlikely to Result in Serious Adverse Health Consequences.

The risk evaluation provided to FDA in our 510(k) submission indicates that the failure of the Care Orchestrator Essence SaMD is not reasonably likely to result in serious injury and all risk are mitigated to acceptable levels (refer to 017_Tab 16F Part 2 CO Essence Risk Matrix 510k of the submission). As part of the risk evaluation (refer to 017_Tab 16F Part 1 – CO Essence Risk Management File 510k), post market and complaint data for comparable patient management software were considered. These analyses included reviews of internal complaint data, and the MAUDE and FDA databases. The analysis concluded that no failure modes of the SaMD or similar patient management system software have resulted in patient harm, death, or otherwise compromised the safety of patients.

In addition to the Care Orchestrator Essence SaMD risk controls, the analysis also considered the inherent safety risk controls of the Trilogy. As noted above, the Trilogy includes multiple validation checks relating to the integrity of the data on the removable media, and once validated requires that the Trilogy user inspects and accepts the changes within the update.

The post-market data for this device further supports that the Care Orchestrator Essence SaMD is not likely to have serious adverse health consequences. For example, to date Respironics has not received any complaints or other reports of events that would require a medical device report for the Care Orchestrator Essence SaMD. Respironics also has not had any reportable field corrections or removals for this device.

For these reasons, the Care Orchestrator Essence SaMD should not be subject to device tracking under Section 519(e) of the FFDCA.

Moreover, even were FDA to disagree that the Care Orchestrator Essence SaMD does not qualify for tracking under Section 519(e), FDA has discretion to exempt the device. FDA's guidance document for Medical Device Tracking[9] states: "FDA has discretion on whether to order tracking for devices that meet the statutory requirements or to release devices from tracking based on additional factors and other relevant information that comes to the Agency's attention." This guidance further notes that FDA may consider information from a variety of sources when deciding whether to add or remove devices form the list of tracked devices, including "recall data, medical device reporting, inspections, petitions, postmarket surveillance or other information coming to its attention."[10] We believe the risk evaluation information provided in the 510(k) submission for K183226, along with the postmarket data described above, support that FDA should exempt the Care Orchestrator Essence device from tracking requirements.

C. Proposed Alternative Steps

Because the Care Orchestrator Essence SaMD is not within the scope of devices described under Section 519(e) that may be subject to tracking orders, alternative steps for device tracking are not required. Nonetheless, as an alternative step, Respironics maintains ship to customer information when DVDs of the Care Orchestrator Essence SaMD are ordered, and similarly retains information on when registered users/customers download the software from the Philips portal.

D. Other Information to Support the Exemption

We further believe that tracking of the Care Orchestrator Essence is unnecessary given its limited use and accessibility. As described above in Section II.A, the Care Orchestrator Essence SaMD is run only on a desktop and is only sold to, used by, and accessible to HCPs, such as physicians, clinicians, and durable medical equipment providers. This SaMD is not used by or accessible to patients. Given this limited distribution, we believe tracking is not necessary for this device.

III. Environmental Impact

The actions requested in this petition are exempt from requirement of an environmental assessment pursuant to 21 C.F.R. §§ 25.30(j) and 25.34(c).

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9 FDA, Center for Devices & Radiological Health, Medical Device Tracking, Guidance for Industry and Food and Drug Administration Staff (Mar. 27, 2014), *available at* https://www.fda.gov/media/71205/download (last visited Apr. 17, 2020).

10 *Id.*

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IV. Economic Impact

Information on the economic impact of this request can be provided if requested.

V. Certification

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes information and views on which the petition relies, and that it includes representative data and information known to the petitioner that are unfavorable to the petition.

Sincerely,

Andy Zeltwanger
Director, Regulatory Affairs
Philips Respironics

c: William H. Maisel, MD, MPH, Director, Office of Product Evaluation and Quality, Center for Devices and Radiological Health (CDRH), FDA
Barbara Zimmerman, Deputy Office Director, Office of Regulatory Programs, CDRH, FDA