PHILIPS

Philips Respironics
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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, cleared under the 510(k) pre-market notification K181053.

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. Respironics received a letter from FDA, dated April 9, 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 is a cloud-based, software as a medical device ("SaMD") product. It is regulated by FDA as a Class II device and was cleared under the pre-market notification K181053. Care Orchestrator was cleared under the following product classification codes: BZD, MNS, MNT, CBK, NOU, and CAW. For the purposes of

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1 21 U.S.C. § 360i(e).

2 *See* Tracking Order for Care Orchestrator Essence (K181053), at Attachment A.

this petition, the term "Care Orchestrator" includes all SaMD covered by K181053, including versions that may be marketed by Respironics using other trade names.

The cleared indications for use under K181053 are set forth below:

> Care Orchestrator is intended to support clinicians by tracking data on patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices. Care Orchestrator provides remote patient data collection & viewing and is intended to be used by healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers) in conjunction with compatible non-life support therapy devices to adjust prescription and/or performance settings. Care Orchestrator allows read-only access to patients. Care Orchestrator is intended to be used in hospital, institutional, provider, and home care settings.[3]

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

> Care Orchestrator 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 system is accessed through a supported Web browser, thereby enabling anytime, anywhere access to patient data. Automatic scoring or diagnosing of a patient's therapy data is not performed by this software.[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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> (A) the failure of which would be reasonably likely to have serious adverse health consequences; or
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> (B) which is –
>
> (i) intended to be implanted in the human body for more than one year, or

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3 *See* Attachment B (FDA clearance letter dated Jan. 4, 2019, Indications for Use statement, and 510(k) Summary).

4 Attachment C (Care Orchestrator 1.26 Help File, at 8).

5 *Id.*

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

Care Orchestrator, however, does not meet the above requirements for a device tracking order.

The Care Orchestrator SaMD is not intended to be implanted, nor is it a life sustaining or life supporting device. Thus, subsections 519(e)(1)(B)(i) and (ii) of the FFDCA are not applicable.

Further, the failure of the Care Orchestrator SaMD is not "reasonably likely to have serious adverse health consequences" under subsection 519(e)(1)(A). As noted above, Care Orchestrator was cleared under K181053 for the following uses:

- To support clinicians by tracking data on patients who are prescribed compatible therapy devices in accordance with the intended use of those therapy devices.
- To provide remote patient data collection and viewing.
- To be used by healthcare representatives (e.g., Physicians, Clinicians, Durable Medical Equipment providers) to adjust prescription and/or performance settings only for non-life support sleep therapy device (BZD, MNS, MNT). This adjustment function is not available for life sustaining/life supporting ventilatory devices (CBK, NOU), or oxygen devices (CAW). Rather, device prescription and settings are read-only for life sustaining/life supporting ventilatory and oxygen devices.
- To provide read-only access to patients.

The failure of the Care Orchestrator SaMD to perform any of the above uses is not "reasonably likely to have serious adverse health consequences." The post-market data for this device further supports that the Care Orchestrator 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 SaMD. Further, the risk evaluation provided to FDA in our 510(k) submission indicates that failure of Care Orchestrator is not reasonably likely and all risk are mitigated to acceptable levels (refer to Tab 16C of the submission).

Moreover, as described in our 510(k) submission and the FDA-cleared 510(k) Summary,[7] the Care Orchestrator SaMD was considered to have a "Moderate" level of concern under FDA's Guidance for the Content of Premarket submissions for Software Contained in Medical Devices (May 2005).[8] That guidance states the following with for a Moderate level of concern:

> "We believe the level of concern is Moderate if a failure or latent design flaw could directly result in minor injury to the patient or operator. The level of concern is also Moderate if a failure or latent flaw could indirectly

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6 21 U.S.C. § 360i(e)(1).

7 *See* Attachment B.

8 *Available at* https://www.fda.gov/media/73065/download (last visited April 16, 2020).

> result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider."[9]

FDA's clearance of the Care Orchestrator SaMD as Moderate level of concern software supports that any failure of the Care Orchestrator software could only "directly result in minor injury" or "indirectly result in minor injury to the patient or operator through incorrect or delayed information or through the action of a care provider." Thus, the failure of the Care Orchestrator SaMD is not "reasonably likely to have serious adverse health consequences" per Section 519(e)(1)(A).

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

C. Proposed Alternative Steps

Because the Care Orchestrator SaMD is not within the scope of devices described under Section 519(e) that may be subject to tracking orders, alternative steps for tracking are not required. However, we note that there are alternative steps that the Respironics may initiate in the event the company determines that a field action may be necessary to address a potential safety issue. For example, because the Care Orchestrator SaMD is a cloud-based software solution and is not distributed to customers (rather, customers access the SaMD solution via a web browser or app store), Respironics is able to promptly implement changes or updates to the SaMD being used by customers, including, label changes (e.g., to the Care Orchestrator help file). We note, however, that no such actions have been required to date to address any potential safety issues for Care Orchestrator.

D. Other Information to Support the Exemption

The Care Orchestrator SaMD is a cloud-based software solution that users may access in a variety of ways, including via a web browser (such as Microsoft Internet Explorer, Google Chrome, or Apple Safari) or through third party app stores, including app stores operated by Apple and Google.[10] Compliance with the device tracking requirements for this type of SaMD product is not practical or feasible, as Respironics does not have contractual relationships with all app distributors to require such distributors comply with, and work with Respironics to ensure compliance with, the requirements under Part 821. For example, Respironics does not have distribution agreements with Apple or Google for that cover compliance with Part 821 when Care Orchestrator access is provided through their respective app stores.

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).

IV. Economic Impact

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9 *Id.* at p. 5. Conversely, the level of concern for software would be considered Major if "a failure or latent flaw could directly result in death or serious injury" or "indirectly result in death or serious injury of the patient or operator through incorrect or delayed information or through the action of a care provider." *Id.*

10 We note that FDA stated in its guidance, Policy for Device Software Functions and Mobile Medical Applications (Sept. 2019), that "distributors may include owners and operators of 'Google Play,' 'iTunes App Store,' and 'BlackBerry App World.'" *Available at* https://www.fda.gov/media/80958/download (last visited Apr. 11, 2020).

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