U.S. FOOD & DRUG ADMINISTRATION

September 14, 2023

Andy Zeltwanger
[redacted]

Sent via email to: [redacted]

Re: Citizen Petition- Docket Number FDA-2020-P-2010

Dear Mr. Zeltwanger:

This letter is in response to the above referenced citizen petition, dated September 22, 2020, that was received and filed with the Food and Drug Administration (FDA or Agency) on September 23, 2020. Your petition states that "Respironics received a letter from FDA, signed October 28, 2019, to track [the Care Orchestrator Essence]" and asks that "FDA issue an exemption from the device tracking requirements under 21 C.F.R. Part 821" for the Care Orchestrator Essence.

On April 7, 2021, FDA sent a letter releasing Philips Respironics from the mandatory tracking requirements of the Tracking Order. For the reasons discussed below, FDA considers your petition moot and is dismissing your petition in accordance with 21 CFR 10.30(e)(3).

I. Statutory and Regulatory Background on Medical Device Tracking

The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended, authorizes FDA under section 519(e) to "by order require a manufacturer to adopt a method of tracking a class II or class III device-

(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."

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In addition, FDA has issued regulations in 21 CFR Part 821 implementing section 519(e) of the FD&C Act. On March 27, 2014, CDRH issued a guidance entitled "Medical Device Tracking: Guidance for Industry and Food and Drug Administration Staff" (Medical Device Tracking Guidance).[1]

II. Discussion

A. Background

The Care Orchestrator Essence software was cleared for use with noncontinuous and continuous ventilators (collectively, compatible therapy devices) under K183226. These compatible therapy devices are all class II devices, regulated under 21 CFR 868.5905 or 868.5895, respectively. The cleared indications for use for the Care Orchestrator Essence state that the software is "intended…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."

B. FDA's Tracking Order Release Letter

CDRH's Office of Product Evaluation and Quality issued an order to Respironics, Inc. on October 28, 2019, for Care Orchestrator Essence ordering that Respironics, Inc. "adopt a method of tracking for [Care Orchestrator Essence], as authorized by section 519(e) of the Federal Food, Drug, and Cosmetic Act (the Act), 21 U.S.C. § 360i(e)."

Upon subsequent review, and consistent with the process and considerations described in the Medical Device Tracking Guidance referenced above, FDA determined that tracking the Care Orchestrator Essence was no longer necessary and on April 7, 2021, issued a letter releasing Philips Respironics from the mandatory tracking requirements.

C. Petition is Moot

FDA can dismiss a petition if the Agency "determines that changes in law, facts, or circumstances since the date on which the petition was submitted have rendered the petition moot." 21 CFR 10.3(e)(3).

The April 7, 2021, letter released Philips Respironics from the obligation to comply with the tracking requirements in section 519(e) of the FD&C Act and 21 CFR Part 821. This represents a change in facts or circumstances since your petition was submitted that renders your petition moot. Therefore, FDA is dismissing your petition.

[1] Available at https://www.fda.gov/media/71205/download.

If you have any questions, please contact Joshua Chetta by e-mail at Joshua.Chetta@fda.hhs.gov or at (240) 402-4910.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2023.09.14 18:53:58 -04'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
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