U.S. FOOD & DRUG ADMINISTRATION

Andy Zeltwanger
Philips Respironics
1740 Golden Mile Highway
Monroeville, PA 15146

Re: Citizen Petition: Exemption from Medical Device Tracking – Docket Number FDA-2020-P-2010

Dear Petitioner:

This is an interim response to the petition dated September 22, 2020, filed by the Food and Drug Administration (FDA) on September 23, 2020. In the petition, you requested that FDA issue an exemption from the device tracking requirements under section 519(e) of the Federal Food, Drug, and Cosmetic Act and 21 CFR Part 821 for software covered by K183226, which includes the Care Orchestrator Essence.

FDA has been unable to reach a decision on your petition because it raises issues requiring further review and analysis by agency officials. This interim response is provided in accordance with FDA regulations (21 CFR 10.30(e)(2) and 821.2). We will respond to your petition as soon as we have reached a decision on your request.

If you have any questions about this interim response, please contact Joshua Chetta in our Office of Policy at (240) 402-4910.

Sincerely yours,

Ellen J. Flannery -S

Digitally signed by Ellen J. Flannery -S
Date: 2020.12.18 13:44:25 -05'00'

Ellen J. Flannery, J.D.
Deputy Center Director for Policy
Director, Office of Policy
Center for Devices and Radiological Health
Food and Drug Administration