



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

Re: Citizen Petition: Exemption from Medical Device Tracking – Docket Number FDA-2020-P-2008

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 K181053, which includes the Care Orchestrator.

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