



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Silver Spring MD 20993

September 24, 2020

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

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting to issue an exemption from the device tracking requirements under 21 C.F.R. Part 821 for the Care Orchestrator Essence was received by this office on 09/23/2020.

It was assigned docket number FDA-2020-P-2010. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter and in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Officer
Dockets Management Staff
FDA/Office of Operations (OO)