January 17, 2021

ResMed Corp
Rose Malonzo
Regulatory Affairs Specialist
9001 Spectrum Center Blvd
San Diego, California 92123

Re: K200565
Trade/Device Name: Galapogos
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 18, 2020
Received: December 18, 2020

Dear Rose Malonzo:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's

requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Rachana Visaria, Ph.D.
Assistant Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200565

Device Name
Galapagos

Indications for Use *(Describe)*
The Galapagos app is intended for patients who are prescribed a compatible ResMed S10 platform device to simulate therapy prior to using their device with their prescribed settings. It is an optional software accessory to allow patients to acclimate to their therapy device.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

[As required by 21 CFR 807.92(c)]

Date of Submission:	13 January 2021
Company Name/Owner:	ResMed Corp 9001 Spectrum Center Blvd San Diego, CA 92123 USA
Official Contact:	Rose Malonzo Specialist, Regulatory Affairs Tel: 858-285-5670 rose.malonzo@resmed.com
Device Trade Name:	Galapagos
Device Common Name:	Ventilator, Non-Continuous (Respirator)
Classification and Classification Name:	II Noncontinuous ventilator (IPPB) (21 CFR 868.5905)
Product Code:	73 BZD
Predicate Device:	Monte Carlo (mobile application in the Menai System) K160836
Device Description:	Galapagos is a mobile interface where the patient can control the device through pre-determined, scaled inspiratory pressures to help them adjust to pressure and mask fit prior to starting their prescribed therapy. In addition, Galapagos may also be used as a communication pathway using the mobile Bluetooth connection to the compatible flow generator in order to send and receive data.
Indications For Use:	The Galapagos app is intended for patients who are prescribed a compatible ResMed S10 platform device to simulate therapy prior to using their device with their prescribed settings. It is an optional software accessory to allow patients to acclimate to their therapy device.

Non-clinical testing

Non-clinical verification and validation testing completed for Galapagos demonstrated that the device met all intended performance requirements. Testing included:

- Software verification and validation
- Predicate testing

The non-clinical performance bench tests performed with Galapagos include testing against the non-functional requirements and end-to-end functional testing. The predicate testing conducted with Galapagos to the predicate Monte Carlo device (K160836) demonstrate substantial equivalence to the technology and operating principle of the devices.

Clinical testing

Clinical tests were not required to demonstrate the safety and effectiveness of Galapagos.

Substantial Equivalence

The subject and predicate device have similar intended use, technology, and operating principle.

The differences between the subject Galapagos device and the previously cleared predicate Monte Carlo app (K160836) are:

- Galapagos can deliver temporary pre-determined therapy settings, whereas Monte Carlo delivers the patient's prescribed therapy settings.
- Galapagos is an optional accessory intended for use by patients to control the compatible flow generator (pre-determined therapy settings), whereas Monte Carlo is a required component of the flow generator device intended as the patient's user interface to control the device, as well as for clinicians to remotely configure the device (i.e., change prescribed therapy settings).
- Via the mobile bluetooth connection and HTTP proxy function, Galapagos is an additional communication pathway to Machine Cloud Service (MCS) of AirView (K151901) to the compatible flow generator in order to send and receive data, similarly to the CAM (cellular) module within the compatible ResMed S10 device. This is considered a non-medical device MDDS function.

Characteristic	**Predicate device:** Monte Carlo **Manufacturer:** ResMed Ltd **510(k) Number:** K160836	**Subject Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Substantial Equivalence**
Indications for Use	Monte Carlo is a mobile application for patients to remotely operate a prescribed compatible ResMed machine and transfer, analyze and display usage and therapeutic information. Monte Carlo also allows healthcare professionals to remotely configure compatible OSA therapy devices.	The Galapagos app is intended for patients who are prescribed a compatible ResMed S10 platform device to simulate therapy prior to using their device with their prescribed settings. It is an optional software accessory to allow patients to acclimate to their therapy device.	Difference in the indications for use does not impact the safety or efficacy of the subject device since the subject device functionality is a limited subset of the predicate.

Characteristic	**Predicate device:** Monte Carlo **Manufacturer:** ResMed Ltd **510(k) Number:** K160836	**Subject Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Substantial Equivalence**
Regulation Number	21 CFR §868.5905	21 CFR §868.5905	Yes. Identical.
Classification Name	Noncontinuous ventilator (IPPB)	Noncontinuous ventilator (IPPB)	Yes. Identical.
FDA Product Code	73 BZD	73 BZD	Yes. Identical.
Prescription Use	Yes	Yes	Yes. Identical.
Intended Environment of Use	Hospital/home	Hospital/Home	Yes. Identical.
Patient Contacting	No, Monte Carlo is software.	No, Galapagos is software.	Yes. Identical.
Display Type	Smartphone display	Smartphone display	Yes. Identical.
Therapy Device Connection Requirement	Yes. Monte Carlo app must be connected to a compatible therapy device for usage.	Yes. Galapagos app must be connected to a compatible therapy device for usage.	Yes. Identical.
Mask Information Requirement	Yes. Monte Carlo app requires patient to provide mask type for usage.	Yes. Galapagos app requires patient to provide mask type for usage.	Yes. Identical.
Performance Testing - Patient Use			
Displays Usage and Therapeutic Values	Yes.	No.	Difference in limited functionality of the subject device does not impact the safety or efficacy of the Galapagos app. The Galapagos app is not intended to alter treatment settings.
Treatment Settings	Ramp time, EPR On/Off	Not available	
Performance Testing - Clinical Use	Same as Patient Use features.	Clinician access not available for Galapagos.	Difference in limited functionality of the subject device does not impact the safety or efficacy of the Galapagos app.
Device Control	Yes. Monte Carlo can control the connected therapy device.	Yes. Galapagos can control the connected therapy device.	Yes. Galapagos has limited device control capabilities as it delivers temporary pre-determined therapy settings, whereas Monte Carlo delivers the patient's prescribed therapy settings.
Communication Pathways Available	Bluetooth and HTTPS (cellular or wireless internet connection)	Bluetooth and HTTPS (cellular or wireless internet connection)	Yes. Identical.

Characteristic	**Predicate device:** Monte Carlo **Manufacturer:** ResMed Ltd **510(k) Number:** K160836	**Subject Device:** Galapagos **Manufacturer:** ResMed Corp **510(k) Number:** K200565	**Substantial Equivalence**
Device data to app communication pathway	Device data transfers directly to Monte Carlo app.	Device data transfers to Machine Cloud Service (MCS) via Galapagos.	Inclusion of MCS in the data pathway does not impact the safety or efficacy of the subject device.
App Download Availability	Apple App Store	Google Play Store	Difference in mobile app store availability does not impact the safety or efficacy of Galapagos.
Therapy Settings Changes	Yes	No	Difference in limited functionality of the subject device does not impact the safety or efficacy of the Galapagos app. The Galapagos app is not intended to alter treatment settings.
Adjust Comfort Settings	Yes	No	Difference in limited functionality of the subject device does not impact the safety or efficacy of the Galapagos app. The Galapagos app is not intended to alter treatment settings.
Level of Concern	Moderate	Moderate	Yes. Identical.

Substantial Equivalence Conclusion

Galapagos has a similar intended use, technology, and operating principle as the predicate device. The differences in the intended use and technology between the subject and predicate devices do not impact or raise new questions of safety or efficacy. The non-clinical performance data provided in this submission supports the determination that Galapagos is substantially equivalent to the predicate Monte Carlo device (K160836).