January 29, 2021

3B Medical, Inc.
Yasser Estafanous
Director of RA/QA
203 Avenue A NW, Suite 300
Winter Haven, Florida 33881

Re: K201620
Trade/Device Name: Luna® G3 BPAP 25A
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: December 17, 2020
Received: December 18, 2020

Dear Yasser Estafanous:

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)*
K201620

Device Name
Luna® G3 BPAP 25A

Indications for Use *(Describe)*
The Luna® G3 BPAP 25A is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single-patient use by prescription in the home or hospital/ institutional environment on adult patients. It is to be used on patients >66lbs/30kg for whom CPAP therapy has been prescribed. The system can deliver bi-level therapy or auto bi-level therapy.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Device Trade Name	Luna® G3 BPAP 25A
Model	LG3700
Common/Usual Name	BPAP System
Date Prepared	January 29, 2021
Sponsor Identification	3B Medical, Inc. 203 Avenue A NW, Suite 300,
Submission Correspondent	Yasser Estafanous 3B Medical, Inc. 203 Avenue A NW, Suite 300, Winter Haven, FL 33881
Phone	863-226-6285
Fax	863-226-6284
Email	yestafanous@3bproducts.com
Establishment Registration #	3008566132
	BMC Medical CO., LTD. Room 901, Building 1, No.28 Pingguoyuan Road, Shijingshan, Beijing 100041, CHINA
Classification	Class II Device (21 CFR 868.5905)
Classification Name	Noncontinuous ventilator
Classification Panel	Medical Device
Products Code	BZD
Medical Specialties	Anesthesiology
Predicate Device(s)	RESmart® BPAP 25A (K133769)

	DreamStation Auto BiPAP (K131982)
Reference Device	Luna® CPAP and Auto CPAP System (K153387)
Reason for Submission:	New Device
Intended Use	The Luna® G3 BPAP 25A is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single-patient use by prescription in the home or hospital/institutional environment on adult patients. It is to be used on patients >66lbs/30kg for whom CPAP therapy has been prescribed. The system can deliver bi-level therapy or auto bi-level therapy.
Device Description	The Luna® G3 BPAP 25A is a microprocessor controlled, blower-based system that generates bi-level positive airway pressure (IPAP/EPAP) to support treatment of obstructive sleep apnea. The system provides fixed or auto-adjust pressure from 4 to 25 cmH_2O above the ambient atmospheric pressure to a patient's oral/nasal airway.

Comparison of Technological Characteristics with the Predicate Devices.

The Luna® G3 BPAP 25A utilizes the same blower and the same algorithm as the primary predicate device RESmart® BPAP 25A (K133769) for respiratory event detection and therapy for sleep disordered breathing events. The subject device and the primary predicate device share the same intended use, same operating principal, and are manufactured and packaged with similar processes. The basic functionality and performance characteristics of the subject device are the same as

the primary predicate device. Compared with the primary predicate device, the subject device includes the following main modifications:

- The humidifier is integrated into the BPAP device, which makes the physical size of the subject device smaller and does not affect the safety or effectiveness of the subject device.

- An optional heated tubing (LH1) is intended to provide warmed and/or humidified breathing gases before entering the patient's airway. The purpose of the heated tubing is to maintain or raise the gas temperature to or above the dew point (of the air exiting the humidifier) reducing or eliminating water condensation and/or pooling of water in the breathing circuit. The biocompatibility of the heated tubing has been tested, and there is no risks of safety or effectiveness.

- The subject device includes an integrated cellular module, which enables the device to upload therapy data to the software iCodeConnect (K160127) managed by the healthcare provider, and the therapy parameters of the device can be adjusted by the healthcare provider through the cellular module. The EMC and wireless coexistence of the cellular module and the cybersecurity of its software are tested and assessed, and there is no risks of safety or effectiveness.

- The subject device provides an AutoCPAP mode in addition to the three therapy modes of the primary predicate device RESmart® BPAP 25A (K133769). The AutoCPAP mode delivers CPAP therapy and provides an air pressure no less than the prescribed one based on the patient's needs. The auto adjusting CPAP algorithm of the AutoCPAP mode is identical to that of the reference device Luna® CPAP and Auto CPAP System (K153387). It did not raise new safety or effectiveness questions.

The predicate device DreamStation Auto BiPAP (K131982) comprises an optional heated tubing and an optional cellular modem. The basic functionality and performance characteristics of the two components of the subject device Luna® G3 BPAP 25A are the same as those of the predicate device

DreamStation Auto BiPAP (K131982). Testings and assessments were conducted on the subject device and they did not raise new safety or effectiveness questions.

The substantial equivalence comparison is provided below.

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
Classification					
Device Classification	Class II Device	Class II Device	Class II Device	Class II Device	Identical to primary predicate
Product Code	BZD	BZD	BZD	BZD	Identical to primary predicate
Classification Panel	Anesthesiology	Anesthesiology	Anesthesiology	Anesthesiology	Identical to primary predicate
Regulation Number	21 CFR 868.5905	21 CFR 868.5905	21 CFR 868.5905	21 CFR 868.5905	Identical to primary predicate
Regulation Name	Noncontinuous ventilator	Noncontinuous ventilator	Noncontinuous ventilator	Noncontinuous ventilator	Identical to primary predicate
Intended Use and Indications for Use					

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
Indications For Use	The Luna® G3 BPAP 25A is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single-patient use by prescription in the home or hospital/institutional environment on adult patients. It is to be used on patients >66lbs/30kg for whom CPAP therapy has been prescribed. The system can deliver bi-level therapy or auto bi-level therapy.	The RESmart® BPAP 25A is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The optional integrated humidifier is indicated for the humidification and warming of air from the flow generator device. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients. It is to be used on patients >66lbs/30kg for whom CPAP therapy has been prescribed. The system can deliver bi-level therapy or auto bi-level therapy.	The DreamStation Auto BiPAP device delivers positive airway pressure therapy for the treatment of Obstructive Sleep Apnea (OSA) in spontaneously breathing patients weighing over 30kg (66 lbs). It is for use in the home or hospital/institutional environment.	The Luna® CPAP and Auto CPAP Systems are intended to deliver positive pressure for the treatment of Obstructive Sleep Apnea (OSA). The optional integrated heated humidifier is indicated for the humidification and warming of air from the flow generator. These devices are intended for single patient use by prescription in the home or hospital/institutional environment on adult patients.	Identical to primary predicate
Pressure Delivery					

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
Therapy Delivered	S， Auto S， CPAP, AutoCPAP	S， Auto S， CPAP	S， Auto S， CPAP	CPAP, AutoCPAP	Similar to primary predicate. Adding the AutoCPAP mode of the reference device does not affect safety or effectiveness.
Pressure Range	For CPAP and AutoCPAP mode: 4.0−20.0 cmH_2O For Auto S and S mode: 4.0−25.0 cmH_2O	For CPAP mode: 4.0−20.0 cmH_2O For Auto S and S mode: 4.0−25.0 cmH_2O	For CPAP mode: 4.0−20.0 cmH_2O For Auto Bi-level mode: 4.0−25.0 cmH_2O	4.0−20.0 cmH_2O	Similar to primary predicate. Pressure range of the AutoCPAP mode is added, which does not affect safety or effectiveness.
Pressure Regulation	±0.5 cmH_2O	±0.5 cmH_2O	±0.5 cmH_2O	±0.5 cmH_2O	Identical to primary predicate
Pressure Display Accuracy (hPa)	±(0.8cmH_2O+4%)	±0.5 cmH_2O	±(0.3cmH_2O＋3.7%)	±(0.5 cmH_2O＋4%)	Similar to primary predicate. Change does not impact safety or effectiveness.
Algorithm					
Automatic adjusting CPAP algorithm	Yes	No	No	Yes	Identical to reference device
Ramp (minutes)	0-60	0-60	0-60	0-60	Identical to primary predicate
Expiratory Pressure Relief	Reslex® function Level 1-3	Reslex® function Level 1-3	Flex® function Level 1-3	Reslex® function Level 1-3	Identical to primary predicate
Humidifier					

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
Integrated	Yes	No	No	No	Both subject and primary predicate devices have a method to attach a humidification system. Change does not impact safety or effectiveness.
Humidity Output	≥15 mg/L, as required by ISO80601-2-74	≥10 mg/L, as required by ISO8185	≥10 mg/L, as required by ISO8185	≥10 mg/L, as required by ISO8185	Similar to primary predicate. Change does not impact safety or effectiveness.
Humidifier Settings	1-5 (95 to 154.4°F/35 to 68°C)	1-5 (104 to 149°F/40 to 65°C)	1 to 5 (95 to 149°F/35 to 65°C)	1-5 (95 to 167°F/35 to 75°C)	Similar to primary predicate. Change does not impact safety or effectiveness.
Delay	Yes	Yes	No	Yes	Identical to primary predicate
Physical Characteristics					
Dimensions	265 × 145×114 mm (with integrated humidifier)	220 x 194 x 112 mm, 313 x 194 x 112 mm (with humidifier)	157 ×193×84 mm, 297×193×84 mm (with humidifier)	170 × 180 × 118 mm, 290×180 × 134 mm (with humidifier)	Dimensions are smaller than primary predicate. No impact on safety and effectiveness.
Weight	1.7kg (with integrated humidifier)	2.2 kg, 3 kg (with humidifier)	1.33kg, 1.98kg (with humidifier)	1.5kg, 2.5kg (with humidifier)	Weight is less than primary predicate. No impact on safety and effectiveness.
AC Power Consumption	100-240V,50/60Hz, 2.0A	100-240V AC, 50/60Hz, 1.0A max	100-240V AC, 50/60 Hz, 2.0-1.0 A	100-240 V AC, 50/60 Hz, 2.0 A max	Similar to primary predicate

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
IEC 60601 Classification	Class II, Type BF	Class II, Type BF	Class II, Type BF	Class II, Type BF	Identical to primary predicate
Degree of Protection Against Water Ingress	IP22	IPX1-Drip-Proof, Vertical	IP22	IP22	IP22 is a more rigorous test than IPX1. Change does not impact safety or effectiveness.
Sound Pressure Level	< 26 dB, when the device is working at the pressure of 10 cmH_2O.	＜30 dB, when the device is working at the pressure of 10 cmH_2O.	Device: 26.1 dB(A) with and uncertainty of 2 dB(A). Device with humidifier: 27.3 dB(A) with and uncertainty of 2 dB(A).	< 30 dB, when the device is working at the pressure of 10 cmH_2O.	The subject device has a lower sound pressure level than the primary predicate, so it is quieter when in use.
Air Filter	Yes	Yes	Yes	Yes	Identical to primary predicate
Non-heated Tubing	Available	Available	Available	Available	Identical to primary predicate
Heated Tubing	Available	Unavailable	Available	Unavailable	Identical to predicate. Testing confirms the biocompatibility of the materials. No impact on safety or effectiveness.
Operating Conditions					
Atmospheric Pressure	760 to 1060 cmH_2O	860 to 1060 cmH_2O	770 to 1010 cmH_2O	760 to 1060 cmH_2O	Similar to primary predicate. No impact on safety or effectiveness.

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
Operating Altitude	0 to 8,000 ft	0 to 8,000 ft	0 to 8,000 ft	0 to 8,000 ft	Identical to primary predicate
Operating Temperature	5°C to 35°C (41˚F to 95˚F)	5 °C to 30° C (41˚F to 86 ˚F)	5°C to 35° C (41˚F to 95 ˚F)	5°C to 35°C (41˚F to 95˚F)	Similar to primary predicate. No impact on safety or effectiveness.
Operating Humidity	15% to 93% Non-condensing	≤ 80% Non-condensing	15% to 95% Non-condensing	15% to 93% Non-condensing	Similar to primary predicate. No impact on safety or effectiveness.
Shipping and Storage Conditions					
Shipping /Storage Temperature	-25°C to 70°C (-13˚F to 158˚F)	-20°C to 55° C (-4˚F to 131˚F)	-20°C to 60°C (-4˚F to 140˚F)	-25°C to 70°C (-13˚F to 158˚F)	Similar to primary predicate. No impact on safety or effectiveness.
Shipping /Storage Humidity	15% to 93% Non-condensing	≤ 93% Non-condensing	15% to 95% Non-condensing	Up to 93% Non-condensing	Similar to primary predicate. No impact on safety or effectiveness.
Data Reporting					
Cellular Module	Available	Unavailable	Available	Available	Identical to predicate. Testing confirm the wireless coexistence and cybersecurity of the subject device. No impact on safety or effectiveness.

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
iCode®	iCode, iCode QR, iCode QR + A feature that is intended to give access to compliance and therapy management information. The iCode consists of six separate codes displayed in the Patient Menu, each code is a sequence of numbers. The “iCode QR” and “iCode QR+” display two-dimensional codes.	iCode A feature that gives access to compliance and therapy management information using encrypted codes. The iCode consists of six separate codes (1 day, 7day, 30 day, 60 day, 90 day, 180day) displayed in the patient menu and retrieved by pressing the humidifier button when the device is not being used.	NA	iCode I, iCode II iCode provides access to the patient's compliance data during a recent time period. The iCode I mode displays data in sequences of characters, and the iCode II mode displays data in two-dimensional codes	Similar to primary predicate. The "iCode QR" and "iCode QR+" display two-dimensional codes, which is a different way of display from the “iCode”. No impact on safety or effectiveness.
iCodeConnect® Software	Available.	Unavailable	NA	Available.	Similar to reference device. Both of them have a method to transmit the patient data to the iCodeConnect software. The difference is the hardware of the module. The subject device uses a 4G kit, while the reference uses a Wifi kit. EMC and cybersecurity have been tested and assessed, and there is no impact on safety or effectiveness.

	Subject Device	Primary Predicate Device	Predicate Device	Reference Device	
	Luna® G3 BPAP 25A (K201620)	**RESmart® BPAP 25A (K133769)**	**DreamStation Auto BiP AP (K131982)**	**Luna® CPAP and Auto CPAP System (K153387)**	**Comparison**
Reuse/Cleaning/Sterility					
Single-patient Use	Yes	Yes	Yes	Yes	Identical to primary predicate
Sterilization/ Reuse	Not provided sterile. Reusable with cleaning instructions	Not provided sterile. Reusable with cleaning instructions	Not provided sterile. Reusable with cleaning instructions	Not provided sterile. Reusable with cleaning instructions	Identical to primary predicate

Non-Clinical Performance Data

The following performance data were used in support of the substantial equivalence determination.

Biocompatibility Assessment:

The Luna® G3 BPAP 25A device is categorized as permanent contact duration (>30 days) with dry and humidified gas pathways. Evaluation and testing were conducted in accordance with the following standards and guidance documents:

• ISO 10993-1:2018 Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
• FDA Guidance Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" June 16, 2016
• ISO 10993-5:2009 Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity
• ISO 10993-10:2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
•ISO 18562-1:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 1: Evaluation and testing within a risk management process
• ISO 18562-2:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 2: Tests for emissions of particulate matter

• ISO 18562-3:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 3: Tests for emissions of volatile organic compounds (VOCs)
• ISO 18562-4:2017 Biocompatibility evaluation of breathing gas pathways in healthcare applications – Part 4: Tests for leachables in condensate

Electrical Safety and Electromagnetic Compatibility:

Testing was conducted on the subject device Luna® G3 BPAP 25A. The system complies with the following standards for electrical safety and EMC:

• AAMI ANSI ES 60601-1:2005/(R)2012 And A1:2012. Medical Electrical Equipment - Part 1: General Requirements for Basic Safety and Essential Performance
• IEC 60601-1-2:2014. Medical electrical equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – requirements and tests
• IEC 60601-1-6:2013. Medical Electrical Equipment - Part 1-6: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Usability
• IEC 60601-1-11:2015. Medical Electrical Equipment - Part 1-11: General Requirements for Basic Safety and Essential Performance - Collateral Standard: Requirements For Medical Electrical Equipment And Medical Electrical Systems Used In The Home Healthcare Environment
• ISO 80601-2-70:2015. Medical electrical equipment Part 2-70: Particular requirements for basic safety and essential performance of sleep apnoea breathing therapy equipment
• ISO 80601-2-74:2017. Medical electrical equipment Part 2-74: Particular requirements for basic safety and essential performance of respiratory humidifying equipment

Software Verification and Validation:

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff:

• "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices"
• "Content of Premarket Submissions for Management of Cybersecurity in Medical Devices"
• "Guidance-Radio Frequency Wireless Technology in Medical Devices"

Mechanical Testing:

Mechanical shock test, Sine vibration, Random vibration test, Drop test, Damp heat test, Dielectric voltage withstand test, Leakage current test.

Results of tests and assessments did not raise new safety or effectiveness questions.

Conclusion

The subject and predicate devices are used for the treatment of obstructive sleep apnea (OSA). They are substantially equivalent in terms of technology and intended use. Risk assessments, biocompatibility evaluation, software evaluation, electromagnetic compatibility and electrical safety, as well as mechanical testing demonstrate that any differences do not raise new questions of safety or effectiveness. The subject device Luna® G3 BPAP 25A is, therefore, substantially equivalent to the predicate device.