May 1, 2020

Globalcare Medical Technology Co., Ltd.
% Kevin Wang
Consultant
Chonconn Medical Device Consulting Co., Ltd.
No. A415, Block A, Nanshan Medical device industrial park,
Nanshan District
Shenzhen, 518067 Cn

Re: K192633
Trade/Device Name: GUS831 Compressor Nebulizer
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer
Regulatory Class: Class II
Product Code: CAF
Dated: April 22, 2020
Received: April 27, 2020

Dear Kevin Wang:

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,

James J. Lee 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)*
K192633

Device Name
GUS831 Compressor Nebulizer

Indications for Use *(Describe)*
GUS831 compressor nebulizer is designed for the production of compressed air to operate a nebulizer kit for the production of medical aerosol for respiratory disorders. The nebulizer kit is intended for multiple use by single patient for single medication. GUS831 compressor nebulizer is intended for domestic use with children from 5 years old, adolescent and adult patients and requires the order of a physician for medical use.

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.

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510(K) Summary

Prepared in accordance with the requirements of 21 CFR Part 807.92

Prepared Date: 2020/02/02

1. Submission sponsor

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2. Submission correspondent

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3. Subject Device Information

Trade/Device Name	Compressor Nebulizer
Model	GUS831
Common Name	Compressor Nebulizer
Regulatory Class	Class II
Classification	21CFR §868.5630 / Nebulizer / CAF
Submission type	Traditional 510(K)

4. Predicate Device

By submission of the Traditional 510(k), Globalcare Medical Technology Co., Ltd. is requesting clearance for Compressor Nebulizer. It is comparable to the following legally marketed system:

1. TaiDoc Technology Corporation, U-RIGHT Compressor Nebulizer under K121969.

The subject device has same intended use, same target patient population, same performance effectiveness, performance safety as the predicate devices and no question is raised regarding to effectiveness and safety. So, the conclusion is that the subject device is substantial equivalent to the predicate.

5. Intended use & Indication for use

GUS831 compressor nebulizer is designed for the production of compressed air to operate a nebulizer kit for the production of medical aerosol for respiratory disorders. The nebulizer kit is intended for multiple use by single patient for single medication. GUS831 compressor nebulizer is intended for domestic use with children from 5 years old, adolescent and adult patients and requires the order of a physician for medical use.

6. Device Description

GUS831 Compressor Nebulizer is a portable aerosol nebulizer electronically powered by an external power

adapter and by an internal rechargeable lithium polymer battery. The compressed air, created by the membrane pump of the device, flows into the nebulizer container kit. The air pressure forced the liquid through the nozzle where it is atomized against a plate within the container. The device is equipped with a mouthpiece to easily delivery the medical aerosol.

7. Principle of Operation

This device operates on the Venturi principle. Compressed air is driven through a converging nozzle, where it accelerates and emerges at a high velocity, creating a vacuum (Venturi effect). The vacuum draws a liquid residing in a reservoir up through a cylindrical channel and into the emerging airstream formed by the nozzle, to mix with air and impact upon a rigid surface. This process uses energy from the airstream to convert liquid into small droplets called aerosol. Upon reaching the user aerosol is suitably refined to enter the lungs effectively.

8. Comparison to the Predicate Device

The GUS831 Compressor Nebulizer and U-RIGHT Compressor Nebulizer (K121969), are identical in purpose, function, core technology and method of operation. Only minor differences exist between the GUS831 Compressor Nebulizer and predicate, which do not affect the safety or effectiveness of the subject device. Table 1 provides a comparison of the subject and predicate devices.

Table 1: Comparison to Predicate Device

Features	**Subject Device** **GUS831 Compressor Nebulizer**	**Predicate Device** **U-RIGHT Compressor Nebulizer**	**Comment**
K number	K192633	K121969	/
Indication for use	GUS831 compressor nebulizer is designed for the production of compressed air to operate a nebulizer kit for the production of medical aerosol for respiratory disorders. The nebulizer kit is intended for multiple use by single patient for single medication. GUS831 compressor nebulizer is intended for domestic use with children from 5 years old, adolescent and adult patients and requires the order of a physician for medical use.	U-RIGHT Compressor Nebulizer, model TD-7013/ TD-7012, is designed to provide a compressed air source to aerosolize physician-prescribed liquid medication when used in combination with the packaged Nebulizer kit, except for Pentamidine. The packaged Nebulizer kit is intended for single use by single patient. U-RIGHT Compressor Nebulizer, model TD-7013/ TD-7012, is intended for use with children, adolescents (5 years to 18 years old), and adult patients in the homecare settings.	Substantially equivalent
Product Code	CAF	CAF	Same
Regulation number	21 CFR §868.5630	21 CFR §868.5630	Same
Panel	Anesthesiology	Anesthesiology	Same
Class	Class II	Class II	Same
Use	Prescription Use	Prescription Use	Same

Features	**Subject Device** **GUS831 Compressor Nebulizer**	**Predicate Device** **U-RIGHT Compressor Nebulizer**	**Comment**
Target Population	>5 years old	>2 years old	Same
Environmental Use	Home use	Homecare setting	Same
Principle of Operation	Compressor Air	Compressor Air	Same
Power source	DC adaptor: 5Vd.c., Internal lithium polymer (Li-Pol) battery: 3.7Vd.c., 2570 mAh	DC adaptor: 6Vd.c.	Substantially equivalent
Power consumption	10W	6W	Difference has no effect on safety or effectiveness
Compressor pressure range (only compressor)	13 ~ 17 psi	15 ~ 17 psi	Difference has no effect on safety or effectiveness
Operating pressure range (with nebulizing chamber)	5.1 ~ 8 psi	6 ~ 8 psi	Difference has no effect on safety or effectiveness
Flow Rate	4 ~ 6 LPM	4 LPM Max.	Substantially equivalent
Noise Level	45 dBA	60 dBA	Difference has no effect on safety or effectiveness
Mode of operation	30 mins on/ 30 mins off	30 mins on/ 30 mins off	Same
Nebulization Rate (avg)	0.25 ml/min	0.25ml/min	Same
Medication capacity	2ml ~ 6ml	2ml ~ 6ml	Same
User interface	On/Off switch LED indicators	On/Off switch	Difference has no effect on safety or effectiveness
Standards met	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11	IEC 60601-1 IEC 60601-1-2	Subject device complies with more recent standards
Patient contact / anatomical site	Mouth	Mouth	Same
Contact materials per ISO 10993-1	External communicating components with tissue contact	External communicating components with tissue contact	Same

Features	Subject Device GUS831 Compressor Nebulizer	Predicate Device U-RIGHT Compressor Nebulizer	Comment
Biocompatibility testing	Cytotoxicity (ISO 10993-5) Irritation (ISO 10993-10) Sensitization (ISO 10993-10) Implantation (ISO 10993-6) Genotoxicity (ISO 10993-3) Gas pathways ISO 18562	Cytotoxicity (ISO 10993-5) Irritation (ISO 10993-10) Sensitization (ISO 10993-10) Implantation (ISO 10993-6) Genotoxicity (ISO 10993-3)	Subject device complies with more recent standards
Dimensions (mm)	68x45x110	125x115x46	Difference has no effect on safety or effectiveness
Weight (Kg)	0.250	0.290	Difference has no effect on safety or effectiveness
Operating conditions	10-40°C 10-95% RH 700-1060 hPa	10-40°C 30-85% RH 700-1060 hPa	Difference has no effect on safety or effectiveness
Storage conditions	-20-60°C 10-95% RH 700-1060 hPa	-25-70°C 10-95% RH 700-1060 hPa	Difference has no effect on safety or effectiveness
Materials	Case: ABS Medicine chamber: PC Nozzle: PP Mouthpiece: HDPE Air tube: PVC	Case: ABS Medicine chamber: PC Nozzle: PP Mouthpiece: HDPE Air tube: PVC	Same
Sterility	No	No	Same
Reusable parts	Nebulizing chamber and mouthpiece Compressor and air tube	Compressor and air tube	Difference has no effect on safety or effectiveness
Device Cleaning	Compressor: Soft dry cloth and non-abrasive cleaners for the outer case of the compressor Kit: wash with soap and hot water after each treatment	Compressor: Alcohol cotton swabs for the outer casing of the compressor Kit: wash with running water or soak in warm water	Difference has no effect on safety or effectiveness
Contraindications	None	Pentamidine	Difference has no effect on safety or effectiveness
Device lifetime	400 hours running time	3 years	Difference has no effect on safety or effectiveness

9. Device Testing

Testing and equivalence analysis were performed to support the substantial equivalence determination.

9.1 Biocompatibility testing

The biocompatibility evaluation for the GUS831 compressor nebulizer was conducted in accordance with the FDA Biocompatibility guidance, 2016 (Use of International Standard ISO 10993-1, "Biological

evaluation of medical devices - Part 1: Evaluation and testing within a risk management process") and International Standard ISO 10993-1 “Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing Within a Risk Management Process,” as recognized by FDA.

All the patient-contacting parts of the GUS831 compressor nebulizer are:

Device: External Communicating (Indirect gas pathway) Tissue / Bone / Dentin communicating

Duration of Use – permanent (> 30 days)

Mouthpiece: Surface Contact Mucosal membrane

Duration of Use – permanent (> 30 days)

The GUS compressor nebulizer use an identical nebulizing kit to U-RIGHT TD-7013, which is already cleared under K121969. Mouthpiece and nebulizing bottle have same formulation and processing, and no other chemicals have been added (e.g., plasticizers, fillers, color additives, cleaning agents, mold, release agents etc.) so new issue regarding biological safety are not raised.

Mouthpiece and nebulizer bottle tests were performed for K121969 clearance as external communicating components with tissue contact:

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-10)
- Genotoxicity (ISO 10993-3)
- Implantation (ISO 10993-6)

9.2 Biocompatibility evaluation of breathing gas pathways

Additional testing pertaining to the gas pathway and associated risk assessments/conclusions were conducted according to the ISO 18562 family of standard by an independent source. Testing included the following assessments:

- Volatile Organic Compound Analysis (VOCs)
- Emitted Particulate Gas Analysis (EPA PM2.5)
- Leachables in condensate (metal ions and organic impurities)

9.3 Aerosol Characterization

Aerosol characterization testing for the subject device and predicate device was conducted in accordance with the relevant sections of the CDRH Guidance Document “Reviewer Guidance for Nebulizer, Metered Dose Inhalers, Spacers and Actuators” (FDA/CDRH – 1993). The particle size distribution test via Cascade Impactor of GUS831 Compressor Nebulizer was performed in comparison to the predicate device K121969 with three drugs (Albuterol sulfate, Ipratropium bromide, Cromolyn sodium). The test has shown almost all the performance parameters of the two different nebulizers were statistically identical for adult conditions and substantially equivalent in the therapeutic amount of medication delivered for pediatric conditions. The measured differences raise no new safety and efficacy issues; therefore, device equivalence is proved.

ADULT CONDITIONS:

Features	**Drug**	**Subject Device GUS831**	**Predicate Device U-RIGHT**
Particle Characterization per Cascade Impactor @ 28 LPM			
Particle Size (MMAD)	Albuterol Sulfate (2.5 mg/3 ml)	2.64±0.35	3.87±0.31

(μm)	Ipratropium Bromide (0.5 mg/2.5 ml)	2.51±0.36	3.37±0.46
	Cromolyn Sodium (20 mg/2.0 ml)	2.64±0.34	2.87±0.15
Geometric Standard Deviation	Albuterol Sulfate (2.5 mg/3 ml)	3.32±0.57	3.77±0.48
	Ipratropium Bromide (0.5 mg/2.5 ml)	3.59±0.48	4.14±0.25
	Cromolyn Sodium (20 mg/2.0 ml)	3.37±0.70	3.70±0.55
Total Dose Delivered (μg)	Albuterol Sulfate (2.5 mg/3 ml)	471±45	514±55
	Ipratropium Bromide (0.5 mg/2.5 ml)	91±9	89±12
	Cromolyn Sodium (20 mg/2.0 ml)	3286±383	2772±441
Total Respirable Dose (0.5-5 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	263±38	259±37
	Ipratropium Bromide (0.5 mg/2.5 ml)	50±8	42±5
	Cromolyn Sodium (20 mg/2.0 ml)	1913±328	1448±312
Coarse Particle Dose (>4.7 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	178±23	253±38
	Ipratropium Bromide (0.5 mg/2.5 ml)	35±6	41±8
	Cromolyn Sodium (20 mg/2.0 ml)	1268±316	1143±106
Fine Particle Dose (<4.7 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	293±45	261±17
	Ipratropium Bromide (0.5 mg/2.5 ml)	56±7	48±4
	Cromolyn Sodium (20 mg/2.0 ml)	2018±430	1628±338
Ultra-Fine Particle Dose (<1.0 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	87±23	56±33
	Ipratropium Bromide (0.5 mg/2.5 ml)	20±3	17±3
	Cromolyn Sodium (20 mg/2.0 ml)	687±133	540±80

PEDIATRIC CONDITIONS:

Features	Drug	Subject Device GUS831	Predicate Device U-RIGHT
Particle Characterization per Cascade Impactor @ 12 LPM			
Particle Size (MMAD) (μm)	Albuterol Sulfate (2.5 mg/3 ml)	5.00±0.95	5.57±0.45
	Ipratropium Bromide (0.5 mg/2.5 ml)	4.57±1.12	6.80±0.61
	Cromolyn Sodium (20 mg/2.0 ml)	4.93±0.47	7.23±0.49
Geometric Standard Deviation	Albuterol Sulfate (2.5 mg/3 ml)	3.00±0.07	3.90±0.29
	Ipratropium Bromide (0.5 mg/2.5 ml)	3.42±0.09	3.74±0.24
	Cromolyn Sodium (20 mg/2.0 ml)	4.35±0.62	3.63±0.79
Total Dose Delivered (μg)	Albuterol Sulfate (2.5 mg/3 ml)	1106±53	1148±69
	Ipratropium Bromide (0.5 mg/2.5 ml)	221±26	232±11
	Cromolyn Sodium (20 mg/2.0 ml)	5523±154	6633±595
Total Respirable Dose (0.5-5 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	541±93	423±15
	Ipratropium Bromide (0.5 mg/2.5 ml)	103±19	79±5
	Cromolyn Sodium (20 mg/2.0 ml)	2370±132	2263±207
Coarse Particle Dose (>4.7 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	576±36	701±107
	Ipratropium Bromide (0.5 mg/2.5 ml)	113±27	152±8
	Cromolyn Sodium (20 mg/2.0 ml)	2920±113	4343±426
Fine Particle Dose (<4.7 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	531±88	447±39
	Ipratropium Bromide (0.5 mg/2.5 ml)	108±32	80±2
	Cromolyn Sodium (20 mg/2.0 ml)	2603±111	2290±478
Ultra-Fine Particle Dose (<1.0 um) (μg)	Albuterol Sulfate (2.5 mg/3 ml)	80±26	51±4
	Ipratropium Bromide (0.5 mg/2.5 ml)	17±5	17±3
	Cromolyn Sodium (20 mg/2.0 ml)	737±51	571±161

10. Conclusion

It has been shown in this 510(k) submission that the difference between the proposed devices and the predicate devices do not raise any questions regarding safety and effectiveness. Performance testing and compliance with voluntary standards demonstrate that the proposed are substantially equivalent to the relevant aspects of the predicate devices in terms of design, components, materials, principals of operation, biocompatibility, performance characteristics, and intended use.