DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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May 19, 2015

Gentec (Shanghai) Corporation
% Mike Gu
Regulatory Manager
Guangzhou Osmunda Medical Device Consulting Co., Ltd
7th Floor, 982 Congyun Road
Baiyun District, 510420 China

Re: K142291
Trade/Device Name: GMX Series Medical Air/oxygen Blender
Regulation Number: 21 CFR 868.5330
Regulation Name: Breathing Gas Mixer
Regulatory Class: Class II
Product Code: BZR
Dated: February 13, 2015
Received: February 18, 2015

Dear Mr. Gu:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

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Clinical Deputy Director
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Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K142291

Device Name
GMX Series Medical Air/Oxygen Blender

Indications for Use *(Describe)*
The GMX Series Medical Air/Oxygen Blender is designed to dispense a continuous blend of Medical Air and Oxygen via outlet ports to infant, pediatric, and adult patients.

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

In accordance with 21 CFR 807.92 the following summary of information is provided:

Date:	May 18,2015
Submitter:	GENTEC (SHANGHAI) CORPORATION No. 1988 Yushu Road, Songjiang District, Shanghai, 201699 ,China
Primary Contact Person:	Mike Gu Regulatory Manager Guangzhou Osmunda Medical Device Consulting Co., Ltd Tel: +86-20-62321333 Fax: +86-20-86330253
Secondary Contact Person:	Lifeng Miao Quality Engineer GENTEC (SHANGHAI) CORPORATION Technology Co., Ltd Tel: +86-21- 67727123-149 Fax: +86-21- 67727176-1759
Device Trade Name:	GMX Series Medical Air/Oxygen Blender
Common/Usual Name:	Oxygen Blender
Classification Name: Product Code:	breathing gas mixer CFR 868.5330 BZR
Predicate Device(s):	Precision Blender (K053232)
Device Description:	The GMX Series Medical Air/Oxygen blender is a restricted medical device intended for use by qualified and trained personnel under the direction of a physician in institutional environments where delivery of air/oxygen mixtures is required. The GMX Series Medical Air/Oxygen blender includes two models: GMX30U-AIR/O_2, GMX120U-AIR/O_2. The GMX Series Medical Air/Oxygen blender is designed, tested, and will be manufactured in accordance with the following standard: ISO 11195 Gas mixers for medical use – Stand-alone gas mixers 1995.
Intended Use:	GMX Series Medical Air/Oxygen Blender is designed to dispense a continuous blend of Medical Air and Oxygen via outlet ports to infant, pediatric, and adult patients.

Technology:

The medical oxygen/air enters the two-stage pressure balancing module through the inlet connectors, each containing a filter and check valves. In the balancing module, the pressures of both gas sources are adjusted and equalized. Then the gases flow into the proportioning module and are mixed according to the oxygen percentage selected.

When the difference in pressure between the two inlet gasses exceeds the prescribed value (or one gas source is disconnected), the bypass poppet which blocks the flow of both gases will move to one side and create a path for the high pressure gas to flow into the alarm channel and generate the audible alarm. Meanwhile, the gas with the higher pressure will flow directly to the outlet port.

When the desired output flow is below the specified range, the bleed valve needs to be activated to ensure the accuracy of oxygen concentration.

Determination of Substantial Equivalence:

The proposed device has the same technological characteristics (i.e. design, energy source) as the predicate device. Both devices accept room air and 100% oxygen gas and, via mechanical means, adjust the molar fraction of oxygen gas in the room air, and blended gas is delivered to the patient, they have identical specifications for the delivery of blended gas and similar specifications for the audible alarm (the pressure differential specification is identical). Both devices are pneumatically powered (supply source, not included) and they produce an audible alarm when the difference in pressure between the two inlet gasses exceeds the prescribed value, or one gas source is disconnected. Neither device is intended to be used sterile, nor do either device contain electrical components.

Please see Table below for more details.

Item	Precision Blender	GMX Series Air/Oxygen Blender
Dimensions	4.9"*2.3"*4.1" (125*57*104mm)	137.5*140*165mm
Weight	1.34 kg	1.5Kg

Oxygen % Range	21-100%	21-100%
Accuracy	±3%	±3%
Energy Source	Air Supply	Air Supply
Supply Pressure	30-75 Psi	30-72.5 psi
Max Flow (GMX120U-AIR/O_2)	≥120 LPM	≥120 LPM
Pressure Drop (GMX120U-AIR/O_2)	≤6psi at 50Psi inlet Pressure and 40lpm flow	≤6psi at 50Psi inlet pressure and 40lpm flow
Alarm/Bypass Reset	≤6psi	≤6psi
Alarm Intensity	0.3meter≥80db	1foot≥80db
Operating Temperature	15℃-40℃	10℃-40℃
Connector	NIST or DISS	NIST or DISS
Max Flow (GMX30U-AIR/O_2)	≥30 LPM	≥30LPM
Pressure Drop (GMX30U-AIR/O_2)	≤6psi at 50Psi inlet Pressure and 10lpm flow	≤6psi at 50Psi inlet pressure and 10lpm flow

The following quality assurance measures were applied to the development of the system:

- Risk Analysis
- Requirements Reviews
- Design Reviews
- Raw materials verification
- Final acceptance testing (Validation)
- Performance testing (Verification)

Summary of Non-Clinical Tests:

The Medical Air/Oxygen Blender complies with voluntary standards :

- ISO 11195 Gas mixers for medical use – Stand-alone gas mixers 1995;
- USP <788>:2012—Particulate Matter in Injections;
- ASTM D 5466-01(2007): Standard Test Method for Determination of Volatile Organic Chemicals in Atmospheres (Canister Sampling Methodology);
- Mechanical Testing as per IEC 60601-1 Medical Electrical Equipment - Part 1: General Requirements For Basic Safety And Essential Performance.

Summary of Clinical Tests:

The subject of this premarket submission, Medical Air/Oxygen Blender, did not require clinical studies to support substantial equivalence.

The proposed device is Substantially Equivalent (SE) to the predicate device which is US legally market device.

Conclusion: GENTEC (SHANGHAI) CORPORATION considers the GMX Series Medical Air/Oxygen Blender to be as safe, as effective, and performance is substantially equivalent to the predicate device(s).