DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 23, 2015

12th Man Technologies, Inc.
Mr. Alex Stenzler
President
7245 Garden Grove Blvd., Suite G
Garden Grove, CA 92841

Re: K142402
Trade/Device Name: BigEasy™ Non-Rebreathing Valve
Regulation Number: 21 CFR 868.5870
Regulation Name: Non-rebreathing valve
Regulatory Class: II
Product Code: CBP
Dated: February 19, 2015
Received: February 23, 2015

Dear Mr. Stenzler:

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
DAGRID/ODE/CDRH FOR

Erin I. Keith, M.S.
Division Director
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Dental Devices
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Center for Devices and
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Enclosure

4. Indications for Use Statement

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K142402
Device Name: BigEasy™

Indications for Use:

The BigEasy™ Non-Rebreathing Valve is intended to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support or cardiopulmonary resuscitation (CPR) rescue techniques.

Prescription Use _X_ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Summary

Submitter's Name	12th Man Technologies, Inc. 7245 Garden Grove Blvd., Suite G Garden Grove, CA 92841 1.714.705.4576
Registration Number	3009108174
Contact Name	Alex Stenzler 12th Man Technologies, Inc. 7245 Garden Grove Blvd., Suite G Garden Grove, CA 92841 Telephone: 1.714.705.4576 Fax: 1.714.373.0505 Email: alex.stenzler@12thmantec.com
Date Prepared	January 11, 2015
Device Trade Name	BigEasy™ Non-Rebreathing Valve
Device Common Name	Non-Rebreathing Valve
Classification Name	Valve, Non-Rebreathing
Product Code	CBP
Device Classification	Class II
Panel	Anesthesiology
Regulatory Classification	21 CFR 868.5870
510(k) Submission	Traditional
Legally Marketed Equivalent	Respironics Rescue Valve/VentEasy Non-Rebreathing Valve (K8337480 and K842693)

Description

The BigEasy™ Non-Rebreathing Valve is a resuscitation valve designed for resuscitation using expired air for ventilation. It has fittings on the patient end that will adapt to standard masks (22mm ID) or endotracheal tubes (15mm OD) used for resuscitation. It provides a path for a rescuer to blow expired air into a mask or endotracheal tube through a silicone valve in the device and has a rigid one-way valve that directs exhaled air from the patient away from the

rescuer. It also incorporates an oxygen inlet port on the rescuer's side of the valve for the adding of supplemental oxygen without requiring a separate adapter.

Predicate Device
The design of the BigEasy non-rebreathing valve is substantially equivalent to the Respironics Rescue Valve (K8337480) and Non-Rebreathing Valve (K842693). The predicate devices are resuscitation valves designed for resuscitation using expired air for ventilation. They all have fittings on the patient end that will adapt to standard masks (22mm ID) or endotracheal tubes (15mm OD) used for resuscitation. They all provide a path for a rescuer to blow expired air into a mask or endotracheal tube through a silicone valve in the device and have a rigid one-way valve that directs exhaled air from the patient away from the rescuer.

The only difference between the predicate device and the BigEasy non-rebreathing valve is that the predicate devices have an accessory fitting for adding oxygen during use while the BigEasy non-breathing valve has the oxygen inlet port molded into the valve body.

Description of Operation
The BigEasy non-breathing valve consists of a plastic body housing a silicone inspiratory one-way valve and a rigid plastic expiratory one-way valve. Rescuers using the BigEasy fill their lungs with room air and then seal their mouth/lips on the BigEasy and blow the air from their lungs into the lungs of the patient requiring resuscitation. When the rescuer blows into the device, the rigid plastic valve moves forward toward the patient and seals the expiratory vent holes. A silicone one-way in the rigid plastic valve plate opens and allows the air from the rescuer to be delivered to the patient. The pressure on the rescuer side of the plastic plate valve is equal or greater than the pressure inside the patient's airways, so the plastic exhalation valve remains closed. When the rescuer stops exhaling into the device, the silicone valve closes, preventing a backflow of air from the patient flowing to the rescuer. The rigid plastic valve now lifts off the expiratory vent hole because the pressure inside the patient's airways are greater than atmospheric pressure. The patient can then passively exhale through the vent holes.

Indications for Use:
The BigEasy™ Non-Rebreathing Valve is intended to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support or cardiopulmonary resuscitation (CPR) rescue techniques.

Specifications	Dimensions: 3.1 x 1.7 x 1.7 inches Inlet Connector: Standard 22mm ID Outlet Connector: Standard 22mm OD/15mm ID Oxygen Port: Standard for respiratory fittings Inspiratory Resistance: 1.9 cm H_2O at 50 LPM Expiratory Resistance: 0.25 cm H_2O at 50 LPM Operating Temperature: -18°C to 50°C Storage Temperature: -40°C to 60°C Storage Relative Humidity: 10% to 95%

Intended Use	The BigEasy™ Non-Rebreathing Valve is intended to assist in providing immediate life support (mouth to mask ventilation) to health emergency victims requiring oxygen support or cardiopulmonary resuscitation (CPR) rescue techniques.

Technology Characteristics Summary

Based on the design, intended use, principle of operation, technological characteristics, performance data, and attribute comparison above, the 12th Man Technologies, Inc. BigEasy™ Non-Rebreathing Valve is substantially equivalent to the Respironics Rescue Valve/VentEasy Non-Rebreathing Valve with the SealEasy Oxygen Adapter. The comparison data show similar values for resistance to flow when compared to the legally marketed device and within the requirements of the identified standards.

Non-clinical test results are submitted to confirm product conformance with device requirements and substantial equivalence to predicate device.

Substantial Equivalency Summary Comparision Table

Features	Respironics Rescue Valve and VentEasy Non-Rebreathing Valve (Predicates)	12th Man Technologies, Inc. BigEasy™ Non-Rebreathing Valve
Intended Use	Mouth to mask ventilation	Mouth to mask ventilation
Target Population	Adult/pediatric patients greater than 18 months of age.	Adult/pediatric patients greater than 18 months of age.
Environment of Use	Hospitals and field emergency	Hospitals and field emergency
Materials	Thermoplastic, Silicone	Thermoplastic, Silicone, TPR (oxygen port cap)
Oxygen port	Accessory adapter	Integrated into the device
Expiratory Resistance	0.25 cm H_2O at 50 LPM	0.7 cm H_2O at 50 LPM
Inspiratory Resistance	1.85 cm H_2O at 50 LPM	1.8 cm H_2O at 50 LPM
Inlet connector	Standard 22mm ID	Standard 22mm ID
Outlet connector	Standard 22mm OD/15mm ID	Standard 22mm OD/15mm ID
Sterile	No	No
Reusable	No. Single patient use device.	No. Single patient use device
Duration of Use	Less than 24 hours	Less than 24 hours
Energy Used/Delivered	Air flow through device used to deliver inspiratory air and exhaled expiratory air from patient.	Air flow through device used to deliver inspiratory air and exhaled expiratory air from patient.
Compatibility	Designed for use with resuscitation masks (Product Code BSJ) and endotracheal tubes with connectors (Product Code BTR).	Designed for use with resuscitation masks (Product Code BSJ) and endotracheal tubes with connectors (Product Code BTR).

Applicable Standards Met

Standard or Regulation	**Standard Organization or Regulatory Body**	**Name of Test Performed**	**Test Results**
AS 4259-1995	Standards of Australia	Ancillary devices for expired air resuscitation	Pass
ISO 13544-2:2002	International Standards Office	Respiratory Therapy Equipment – Part 2: Tubing and Connectors	Pass
ISO 5356-1:2004	International Standards Office	Anaesthetic and Respiratory Equipment – Conical Connectors – Part 1: Cones and Sockets	Pass
BS EN ISO 10651-4:2009	International Standards Office	Lung Ventilators – Part 4: Particular requirements for operator-powered non-rebreathing valves	Pass
ISTA-2A:2011	National Institute for Occupational Safety and Health	Packaged-Products weighing 150 lbs (68 kg) or Less	Pass
ISO 10993-1:2009 COR 1 2010	International Standards Office	Biological Evaluation of Medical Devices – Part 1: Evaluation and Testing within a Risk Management Process	Pass
FDA Guidance Document (Draft)	FDA	Draft Reviewer Guidance on Face Masks and Shield for CPR	Pass
BS EN ISO 15223-1:2012	International Standards Office	Medical Devices – Symbols to be used with Medical Devices Labels, Labelling and Information to be supplied– Part 1: General Requirements	Pass
EPA-453/R-98-008B	Environmental Protection Agency	Method TO-15, Determination Of Volatile Organic Compounds (VOCs) In Air Collected In Specially-Prepared Canisters And Analyzed By Gas Chromatography/ Mass Spectrometry (GC/MS)	Pass

Performance Testing

Biocompatibility testing

Biocompatibility Test	ISO 10993-1 Requirement	Test Results
Cytotoxicity	Required	Passes
Irritation	Required	Passes
Sensitization	Required	Passes

Summary Table of Testing Performed to the Applicable Standards Listed

Bench Test	Purpose	Pass/Fail Results	Justification
Packaging and Assembly / Shipping	To verify the device meets packaging and assembly / shipping requirements	Pass	The BigEasy™ Non-Rebreathing Valve met the packaging and assembly / shipping testing acceptance criteria.
Environmental	To verify the device meets environmental requirements	Pass	The BigEasy™ Non-Rebreathing Valve met the environmental requirements acceptance criteria.
VOC's, Ozone, CO, CO_2 and Fine Particle Discharge	To verify that the device meets TO-15 standards for VOC's and requirements for the discharge of other gases and particles below the standards' thresholds	Pass	The BigEasy™ Non-Rebreathing Valve met the requirements for VOC's, Ozone, CO, CO_2, and Fine Particles.
Materials Specifications	To verify the device meets the materials specifications requirements	Pass	The BigEasy™ Non-Rebreathing Valve met the materials specifications acceptance criteria.
Labeling Verification	To verify the device meets the labeling verification requirements	Pass	The BigEasy™ Non-Rebreathing Valve met the labeling verification acceptance criteria.
Inlet and Outlet Fittings	To verify the device meets the inlet and outlet fitting requirements	Pass	The BigEasy™ Non-Rebreathing Valve met the fittings acceptance criteria.
Biocompatibility	To verify the device meets the biocompatibility requirements	Pass	Based on ISO10993-1:2009/2010 and the 2013 FDA Guidance Document, the BigEasy™ Non-Rebreathing Valve meets the biocompatibility acceptance criteria.
Resistance to inhalation and exhalation after and during environmental exposure, vomitus contamination, water submersion and mechanical displacement.	To verify the device meets the inhalation and exhalation resistance requirements	Pass	The BigEasy™ Non-Rebreathing Valve met the resistance criteria.
Drop test from 1 meter	To verify that the valve can withstand a drop on a concrete floor	Pass	The BigEasy™ Non-Rebreathing Valve met the drop test requirements
Mean concentration of oxygen at 15 LPM and circuit backpressure at 30 LPM	To determine the mean oxygen concentration and the backpressure during oxygen delivery	Pass	The BigEasy™ Non-Rebreathing Valve met the requirements for oxygen delivery.
Assembly and Application	To validate the device can be assembled and applied according to the IFU	Pass	Participants were able to perform the intended actions while following the IFU

Substantial Equivalence

12th Man Technologies, Inc. has demonstrated that the proposed device (BigEasy Non-Rebreathing Valve) is as safe and as effective as the predicate device. It is considered to be substantially equivalent to the currently marketed predicate device which has been previously reviewed for market clearance by the FDA.

K142402 .

Premarket Notification [510(k)] Number