DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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September 5, 2017

BMC Medical.,Ltd.
% Alex Lucio
Executive Vice President
3B Medical Inc.
799 Overlook Drive,
Winter Haven, Fl 33884

Re: K163464
Trade/Device Name: Viva Nasal Mask (Model: NM4), Numa Full Face Mask (Model: BMC-FM2)
Regulation Number: 21 CFR 868.5905
Regulation Name: Noncontinuous Ventilator (IPPB)
Regulatory Class: Class II
Product Code: BZD
Dated: July 19, 2017
Received: July 24, 2017

Dear Alex Lucio:

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,

Michael J. Ryan -S

for Lori A. Wiggins, MPT, CLT
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K163464

Device Name
Viva Nasal Mask (Model: NM4)
Numa Full Face Mask (Model: BMC-FM2)

Indications for Use *(Describe)*

The Viva Nasal Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.
The Viva Nasal Mask is:
□To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.
□Intended for single-patient reuse.

The Numa Full Face Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.
The Numa Full Face Mask is:
□ To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.
□ Intended for single-patient reuse.

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

510(k) Owner:

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Contact Person: Jiang Huiqi

Submission Date: November 15, 2016

Submission Correspondent:

Name: Alex Lucio
Executive Vice President

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Phone: 863-226-6284

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Applicant Device Information:

Trade Name: Viva Nasal Mask (Model: NM4)
Numa Full Face Mask (Model: BMC-FM2)

Common Name: Vented Face Mask

Name/Classification: Accessory to Non-Continuous Ventilator

Product Code: BZD

Regulation Number: 21CFR 868.5905

Device Class: II

Predicate Device(s)

Predicate Device of Viva Nasal Mask: BMC-NM2 Nasal Mask (K133009)

Predicate Device of Numa Full Face Mask: Quattro™ Air (K123979)

Reference Device

BMC Willow Mask, K112277

Device Description

Viva Nasal Mask

Viva Nasal Mask provides an interface such that airflow from a positive pressure source is directed to the patient's nose. The masks are held in place with adjustable headgear that straps the mask to the face. Viva Nasal Mask has plastic body and silicone seal that touches the face and includes a pad that rests on the forehead.

The Viva Nasal Mask is a prescription device supplied non-sterile.

Numa Full Face Mask

Numa Full Face Mask provides an interface such that airflow from a positive pressure source is directed to the patient's mouth and nose. The masks are held in place with adjustable headgear that straps the mask to the face. Numa Full Face Mask has plastic body and silicone seal that touches the face and include an adjustable pad that rests on the forehead.

Numa Full Face Mask is a prescription device supplied non-sterile.

Indications for Use

The Viva Nasal Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system.

The Viva Nasal Mask is:

- To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.
- Intended for single-patient reuse.

The Numa Full Face Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system.

The Numa Full Face Mask is:

- To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed.
- Intended for single-patient reuse.

Table 1: Technical Comparison to the Predicate Device

1.1 Comparison Table1 (Viva (Model: NM4) K163464to BMC-NM2 Nasal Mask (K133009))

Comparison Elements		Applicant Device Viva (Model: NM4)K163464	Predicate Device BMC-NM2 (K133009)	Comparison Statement
Device name		Nasal Mask	Nasal Mask	Same classification information
Classification name		Accessory to Non-Continuous Ventilator	Accessory to Non-Continuous Ventilator	
Product code		BZD	BZD	
Indications for Use		The Viva Nasal Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or bi-level system. The Viva Nasal Mask is: To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed. Intended for single-patient reuse.	The BMC-NM2 Nasal Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system. The BMC-NM2 Nasal Mask is: To be used by adult patients (>30 kg) for whom positive airway pressure has been prescribed. Intended for single-patient re-use in home environment and multi-patient reuse in the hospital/institutional environment.	Different. The inclusion of “single-patient reuse” is a narrower indication to the “multi-patient, multi-use” in the hospital / institutional environment and does not alter the intended use of the device.
Target population		Adult (>66lbs / >30kg)	Adult (>66lbs/30kg)	Same
Patient usage type		Single-patient reuse	Single-patient reuse in home environment and multi-patient reuse in the hospital/institutional environment.	Different. The inclusion of “single-patient reuse” is a narrower indication to the “multi-patient, multi-use” in the hospital / institutional environment and does not alter the intended use of the device.
Anatomical site		Nose	Nose	Same
Provided sterile or non-sterile		Not sterile	Not sterile	Same
Design		Nasal interface and headgear	Nasal interface and headgear	Same
Number of mask size		Three sizes (small, medium, and large)	Three size (small, medium, and large)	Same
Patient circuit connection		22mm entrainment valve elbow	22mm entrainment valve elbow	Same
Device Specifications	Therapy Pressure range	4 to 25 hPa	4 to 30 hPa	Different. This difference will not raise new risks, as pressure range is within subset of predicate.

Comparison Elements		Applicant Device Viva (Model: NM4)K163464	Predicate Device BMC-NM2 (K133009)	Comparison Statement
	Intentional leak(Passive Exhalation Port Flow)	4hPa=19 L/min 8hPa=28L/min 12hPa=35L/min 16hPa=41L/min 20hPa=46L/min 25hPa=51L/min	4hPa=20L/min 12hPa=40L/min 20hPa=51L/min 30hPa=72L/min	Different. International leak is actually to exhale CO_2. Under the same pressure, subject device's intentional leak is slightly smaller than that of predicate device. This difference has little impact on CO_2 rebreathing. The subject device has passed CO_2 rebreathing testing according to ISO 17510-2:2007. Please refer to "Appendix E_CO_2 Rebreathing Testing". Hence, this difference will not introduce any additional risk to the user.
	Dead space	S Size: 76ml M Size: 83ml Large Size: 92ml	S Size: 124ml M Size: 129ml Large Size:135ml	Different. The dead space of three sizes is less than that of the predicate. All seal sizes are in conformance with ISO 17510-2:2007 and this difference does not introduce any additional risk to the user.
	Resistance/ Pressure Drop	at 50L/min: 0.2 hPa at 100L/min: 0.8 hPa	at 50 L/min: 0.2 hPa at 100 L/min: 0.5 hPa	Same.
	Operating environment	5 to 40℃ 10% to 93% relative humidity, non-condensing	5 to 40℃ 10% to 93% relative humidity, non-condensing	Same.
	Storage environment	-20 to +55℃ 10% to 93% relative humidity, non-condensing	-20 to +55℃ 10% to 93% relative humidity, non-condensing	Same.
Materials		Polycarbonate Silicon	Polycarbonate Silicon	Same materials for BMC's Willow Nasal Mask (K112271) Cleared previously for substantially equivalent intended use.

Comparison Elements	Applicant Device	Predicate Device	Comparison Statement
	Viva (Model: NM4)K163464	**BMC-NM2 (K133009)**	
	Nylon & Spandex Fabric	Nylon & Spandex Fabric	
	Polypropylene	——	

1.2 Comparison Table 2 (Numa (Model: BMC-FM2) K163464 to Quattro^{TM}Air(K123979))

Comparison Elements	Applicant Device	Predicated Device	Conclusion
	Numa (Model: BMC-FM2)K163464	**Quattro^{TM}Air(K123979)**	
Device name	Full Face Mask	Full Face Mask	Same classification information
Classification name	Accessory to Non-Continuous Ventilator	Accessory to Non-Continuous Ventilator	
Product code	BZD	BZD	
Indications for Use	The Numa Full Face Mask channels airflow noninvasively to a patient from a positive airway pressure device such as a continuous positive airway pressure (CPAP) or Bi-level system. The Numa Full Face Mask is: To be used by adult patients (>66lbs / >30kg) for whom positive airway pressure has been prescribed. Intended for single-patient reuse.	The Quattro Air is a noninvasive accessory used for channeling airflow (with or without supplemental oxygen) to a patient from a positive airway pressure (PAP) device such as a continuous positive airway pressure (CPAP) or bilevel system. The Quattro Air is: to be used by patients (weighing >30 kg) for whom positive airway pressure therapy has been prescribed intended for single-patient reuse in the home environment and multipatient reuse in the hospital/institutional environment..	Different. The inclusion of "single-patient reuse" is a narrower indication to the "multi-patient, multi-use" in the hospital / institutional environment and does not alter the intended use of the device.
Target population	Adult (>66lbs / >30kg)	Adult (>66lbs/30kg)	Same
Patient usage type	Single-patient reuse	Single-patient re-use in the home environment and multi-patient re-use in the hospital/institutional environment	Different. The inclusion of "single-patient reuse" is a narrower indication to the "multi-patient, multi-use" in the hospital / institutional environment and does not alter the intended use of the device.
Anatomical site	Nose and mouth	Nose and mouth	Same

Comparison Elements		Applicant Device Numa (Model: BMC-FM2)K163464	Predicated Device Quattro™Air(K123979)	Conclusion
Provided sterile or non-sterile		Not sterile	Not sterile	Same
Design		face interface and headgear	face interface and headgear	Same
Number of mask size		Three sizes (small, medium, and large)	Four sizes (extra small, small, medium, and large)	Similar. The predicate is available in an additional extra small size. The additional size is an optional sizing option. That has no correlation to safety or effectiveness.
Patient circuit connection		22mm entrainment valve elbow	22mm entrainment valve elbow	Same
Device Specifications	Therapy Pressure range	3 to 40hPa	3 to 40 hPa	Same
	Intentional leak(Passive Exhalation Port Flow)	3 cm H2O =18L/min 4 cm H2O =22 L/min 8 cm H2O =32 L/min 10 cm H2O=36 L/min 12 cm H2O =40L/min 16 cm H2O =47 L/min 20 cm H2O =53 L/min 25 cm H2O =60 L/min 30 cm H2O =65 L/min 35 cm H2O =71L/min 40 cm H2O =78 L/min	3 cm H2O =19 L/min 4 cm H2O =22 L/min 8 cm H2O =32 L/min 12 cm H2O =41 L/min 16 cm H2O =48 L/min 20 cm H2O =54 L/min 24cm H2O =60L/min 28cm H2O =66L/min 30 cm H2O =69 L/min 32cm H2O =72L/min 36cm H2O =72L/min 38cm H2O =77L/min 40cm H2O =82 L/min	Different. International leak is actually to exhale CO_2. Under the same pressure, subject device's intentional leak is slightly smaller than that of predicate device. This difference has little impact on CO_2rebreathing. The subject device has passed CO_2rebreathing testing according to ISO 17510-2:2007. Please refer to "Appendix E_CO2 Rebreathing Testing". Hence, this difference will not introduce any additional risk to the user.
	Dead space	S Size: 171ml M Size: 192ml Large Size: 218mL	S Size: 176ml M Size: 198ml Large Size: 222mL	Different. The dead space of three sizes is less than that of the predicate. All seal sizes are in conformance with ISO 17510-2 (2007) and this difference does not introduce any additional risk to the

Comparison Elements		Applicant Device	Predicated Device	Conclusion
		Numa (Model: BMC-FM2)K163464	**Quattro™Air(K123979)**	
				user.
	Resistance/ Pressure Drop	at 50L/min: 0.15 cm H_2O at 100L/min: 0.5 cm H_2O	at 50 L/min: 0.1 cm H_2O at 100 L/min: 0.4 cm H_2O	Testing is performed and results from this testing concluded that the verification testing raises no new issues of safety or effectiveness.
	Inspiratory and expiratory resistance (with Anti Asphyxia Valve open to atmosphere)	Inspiration at 50 L/min: 1.8 cm H2O Expiration at 50 L/min: 2.0 cm H2O	Inspiration at 50 L/min: 0.2cm H2O Expiration at 50 L/min: 0.9 cm H2O	Different. Testing is performed according to ISO 17510-2:2007 and results are all less than 10cmH2O required in Clause 5.5 of ISO 17510-2:2007. Hence, testing shows inspiratory and expiratory resistance are substantially equivalent .
	Operating environment	5 to 40℃ 10% to 93 % relative humidity non-condensing	5°C to 40°C 15% to 95% relative humidity non-condensing	Similar. This difference will not raise new risks.
	Storage and transport environment	-20 to +55℃ 10% to 93% relative humidity, non-condensing	-20 to +60℃ 0% to 95% relative humidity, non-condensing	Different. The labeled maximum for storage and transport environment is a few degrees at the outside maximum. This difference will not raise new risks.
Materials		Silicon	Silicon	As predicate device is manufactured by a different manufacturer, formulations are unknown. Leveraging K112271, also manufactured by BMC Medical, for biocompatibility. The materials used in K112271 are identical to the materials used in the proposed device.
		Nylon & spandex Fabric	"Breathoprene" Fabric	
		Polycarbonate	Molded Plastic	
		Polypropylene	——	

Performance Data

Non-Clinical Testing

Performance testing has been carried out in conformance with ISO 17510-2 to verify the performance of the Viva Nasal Mask and Numa Full Face Mask. The results of performance data show that the Viva Nasal Mask is substantially equivalent to its predicate mask -- BMC-NM2 Nasal Mask (K133009), and the Numa Full Face Mask is substantially equivalent to its predicate mask -- Quattro™ Air (K123979)

The performance bench testing includes:

Passive exhalation port flow, the resistance to flow, anti-asphyxia valve related testing, dead space, CO_2 rebreathing, ISO 17510-2 testing, transportation, and accelerated aging and shelf life.

The CO_2 performance of the new device was tested to ensure the mask design provides adequate venting to flush out the expired CO_2. The testing included physical and functional dead-space, measurements. The device was shown to be substantially equivalent to the predicate devices. The Anti-Asphyxia Valve (AAV) performance was tested to ensure the patient can continue to breathe fresh air if ever the airflow from the flow generator is impeded. The device was shown to be substantially equivalent to the predicate devices.

The pressure-flow characteristics and through impedance of the mask were tested to ensure clinicians are able to prescribe the appropriate therapy using the new device. The device was shown to be substantially equivalent to the predicate devices. The mechanical integrity and performance of the new device was tested during normal use and reasonable abuse scenarios. The device was also tested to demonstrate that the mask can withstand the effects of storage temperature, humidity and transportation shock & vibration.

All the materials used in the manufacturing of the Viva Nasal Mask and Numa Full Face Mask are identical to the materials used in BMC's legally marketed Willow Mask (K112271) under same conditions.

In conclusion, the test reports demonstrate that the Viva Nasal Mask and Numa Full Face Mask are substantially equivalent to the predicate devices.

Clinical Test

No clinical testing was performed; use of full face mask and nasal mask with CPAP or bi-level therapy is proven technology and is well accepted by the medical community.

Conclusion

Substantial Equivalence Conclusion

The Viva Nasal Mask and Numa Full Face Mask are substantially equivalent to the predicate devices:

-they have similar indications for use;
-they have similar technological characteristics to the predicate devices;
-they do not raise any new questions of safety or effectiveness;
-they are substantially equivalent to the predicate devices.