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

January 9, 2015

Vectura GmbH
c/o Paul Dryden
Consultant
Robert-Koch-Allee 29
Gauting, Germany 82131

Re: K142059
Trade/Device Name: FOX MOBILE
Regulation Number: 21 CFR 868.5630
Regulation Name: Nebulizer (Direct Patient Interface)
Regulatory Class: Class II
Product Code: CAF
Dated: December 11, 2014
Received: December 12, 2014

Dear Mr. Dryden:

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" (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 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.

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

Erin I. Keith, M.S.
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: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*

K142059

Device Name

FOX MOBILE

Indications for Use *(Describe)*

The FOX MOBILE inhalation system is a nebulizer system that will be used with patients for whom doctors have prescribed medication for nebulization in the home care, nursing home, sub-acute institution, or hospital environments. It is intended for patients 3 years and older who can coordinate breathing.

Type of Use *(Select one or both, as applicable)*

XX Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Attachment # 26

510(k) Summary

Date Prepared: 11-Dec-14

Vectura GmbH
Robert-Koch-Allee 29
82131 Gauting, GERMANY

Tel – +49 89 89 79 69 Ext 19
Fax – +49 89 89 79 69 22

Official Contact: Raimund Gleixner
Director of Regulatory Affairs, Devices

Proprietary or Trade Name: FOX MOBILE

Common/Usual Name: Nebulizer (Direct Patient Interface)

Classification Name: Nebulizer (Direct Patient Interface)
Product Classification – CAF
21 CFR 868.5630
Class II

Predicate Devices: K072019 – Activaero (Vectura) - AKITA² APIXNEB
K935693 – Vortran – AutoNeb

Device Description:
The FOX MOBILE is a single patient, multi-use, handheld inhalation system to deliver medications which are to be aerosolized. The system includes:

- A vibrating mesh nebulizer
- LEDs for user feedback
- Flow limitation valve (LIMIX)
- Air control

Indications for Use:
The FOX MOBILE inhalation system is a nebulizer system that will be used with patients for whom doctors have prescribed medication for nebulization in the home care, nursing home, sub-acute institution, or hospital environments. It is intended for patients 3 years and older who can coordinate breathing.

Comparison to Predicates
We have chosen two (2) predicates for our substantial equivalence claim. The following is a rationale for this selection.

- K072019 – Activaero - AKITA² APIXNEB
- K935693 – Vortran - AutoNeb

Table 1 is a table which highlights the reason for selecting each predicate.

Substantial Equivalent Elements	**K072019 Activaero - AKITA² APIXNEB**	**K935693 Vortran - AutoNeb**
Indications for Use	X	X
Environment of Use	X	X
Patient Population	X	X
Technology of vibrating mesh for nebulizing drugs	X	Jet nebulizer
Synchronized delivery of nebulizer drug	X	X
Drug delivery on demand	X	X
Adjustable inhalation times that are breathe activated	X Pre-set Smart Cards	X Manual
Patient can adjust inhalation times		X

Table 2 Compares the FOX MOBILE to Activaero - AKITA² APIXNEB (K072019)

Attribute	**Activaero AKITA² APIXNEB (K072019)**	**Proposed FOX MOBILE**
Indications for Use	The AKITA² APIXNEB is a nebulizer system that will be used with patients for whom doctors have prescribed medication (except pentamidine) for nebulization in the home care, nursing home, sub-acute institution, or hospital environment. The AKITA² APIXNEB is intended for patients 3 years and older who can coordinate breathing.	The FOX MOBILE inhalation system is a nebulizer system that will be used with patients for whom doctors have prescribed medication for nebulization in the home care, nursing home, sub-acute institution, or hospital environments. It is intended for patients 3 years and older who can coordinate breathing.
Single patient, multi-use	Yes	Yes
Basic components	Control unit Disposable reservoir with cap Disposable aerosol generator Disposable Mouthpiece	Base unit Disposable reservoir with nebulizer Disposable Cap Disposable Mouthpiece
Technology, Features and Specifications		
Nebulizer technology	Vibrating mesh	Vibrating mesh
Synchronized delivery of nebulized drug	Yes	Yes
Drug delivery on demand	Yes	Yes
Inhalation Volume (times)	2 – 8 seconds	1.5 to 8 seconds
Gas source	Compressor	Self-generated by user
Flow rate	15 lpm	15 lpm
Power source	Mains	Battery AC

Attribute	Activaero AKITA² APIXNEB (K072019)	Proposed FOX MOBILE
Performance testing	Particle characterization Comparison results found to be equivalent	Particle characterization Mechanical Environmental Simulated lifetime cycle (cleaning) Differential Pressure IEC 60601-1 plus deviations IEC 60601-1-2 IEC 60601-1-6 IEC 60601-1-11

Table 3 – Compares FOX MOBILE to Predicate – Vortran - AutoNeb (K935693)

Attribute	Predicate Vortran AutoNeb K935693	Proposed FOX MOBILE
Indications for Use	Not listed but a general purpose nebulizer	The FOX MOBILE inhalation system is a nebulizer system that will be used with patients for whom doctors have prescribed medication for nebulization in the home care, nursing home, sub-acute institution, or hospital environments. It is intended for patients 3 years and older who can coordinate breathing.
Environments of use	Not specified but includes home care setting	home care, nursing home, sub-acute institution, or hospital environment
Patient population	All – not specified	patients 3 years and older who can coordinate breathing
Technology	Jet nebulizer	Vibrating mesh
Operational Flow Rate	1.5-16 LPM	15 LPM
Synchronized delivery of nebulized drug	Yes	Yes
Mode of Operation	Breathe activated	Breathe activated
Drug delivery triggered by	Patient Inhalation Pressure signal	Patient Inhalation Pressure signal
Adjustable Inhalation times	0.5 – 9.9 sec – patient adjustable	1.5 – 8 sec – patient adjustable

Substantial Equivalence Discussion

Tables 2 to **3** above compare the key features of the proposed FOX MOBILE with the identified predicates and demonstrates that the device can be found to be substantially equivalent. In summary one can conclude that substantial equivalence is met based upon the following:

Indications for Use –
The indications for use are identical for the proposed device when compared to the predicate – K072019 – AKITA² APIXNEB. The predicate K935693 – AutoNeb does not have published indications but is known to be similar as a general purpose nebulizer.
Discussion – Each device is indicated for use as a general purpose nebulizer.

Technology and construction –
The nebulizer technology is identical to the predicate – K072019 - AKITA² APIXNEB**.** The basic design, fabrication, etc. are equivalent to the predicates as a handheld nebulizer.
Discussion – The design, vibrating mesh nebulizer technology, controlled inhalation flow and adjustable inhalation times are all similar to the predicate K072019 - AKITA² APIXNEB**.** There is a difference in the power source between the 2 devices. The FOX MOBILE is operated by a rechargeable battery while the predicate K072019 - AKITA² APIXNEB is powered by standard AC power. The use of battery power to operate a device is common and this difference does not raise any new safety concerns.

Patient Control Features –
The ability of the user to change or adjust inhalation times is substantially equivalent to the predicate K935693 – AutoNeb**.**

In addition the design of drug delivery on demand, synchronized with inhalation, controlled inhalation flow, user feedback as to how they are performing during inhalation are very similar to the predicate K072019 - AKITA² APIXNEB while some features are equivalent to the predicate K935693 – AutoNeb.
Discussion – This difference of adjusting the inhalation times between the FOX MOBILE and the predicate K935693 – AutoNeb is that the FOX MOBILE has pre-sets that the user selects, while the predicate AutoNeb, the user makes manual adjustments between the high and low inhalation time range. This difference in how the patient adjusts the inhalation time does not raise new safety issues.

Environment of Use –
The environments of use are identical to both predicates - K072019 - AKITA² APIXNEB and K935693 – AutoNeb**.**
Discussion – Both devices are used in the home care, nursing home, sub-acute institution, or hospital environments settings.

Patient Population –
The patient population is identical to the predicate - K072019 - AKITA² APIXNEB**.**
Discussion – The patient populations are equivalent to K072019 - AKITA² APIXNEB**.** The patient populations are believed to be equivalent to the predicate K935693 – AutoNeb but there is little available information.

Non-clinical Testing Summary –

Particle Characterization –
We performed comparative particle characterization testing via Cascade Impactor and the results demonstrated equivalent performance to the predicate K072019 - AKITA² APIXNEB**.**

Materials –
We have tested the materials per ISO 10993-1 and the results supported the material satisfying the requirements. Testing included, Cytotoxicity, Sensitization, Genotoxicity, Implantation, Systemic Toxicity, Subchronic toxicity, Leachable and Extractable at 50°C for 72 hours, VOC and $PM_{2.5}$ with a complete Risk Based Assessment.
Discussion – We have tested the materials which are commonly used in nebulizers.

Table 4 – Summary of Comparative Particle Characterization for FOX MOBILE vs. AKITA² APIXNEB (K072019) – Adult flow rate – 15 lpm (Confidence interval of 95%)

Particle characterization	Drug	FOX MOBILE	AKITA² APIXNEB (K072019)
MMAD (um)	Sultanol CromoHEXAL Atrovent	4.0 ± 0.1 4.0 ± 0.1 4.0 ± 0.1	4.6 ± 0.1 4.6 ± 0.1 4.3 ± 0.1
GSD	Sultanol CromoHEXAL Atrovent	1.65±0.01 1.69±0.03 1.67±0.02	1.70±0.06 1.72±0.15 1.63±0.03
Total Delivered Dose by Device (mg)	Sultanol CromoHEXAL Atrovent	2.22 ± 0.08 17.8 ± 0.3 0.48 ± 0.01	2.23 ± 0.10 18.4 ± 0.5 0.48 ± 0.01
Total Respirable Dose (< 5 um) (%)	Sultanol CromoHEXAL Atrovent	67.7% ± 1.1 66.2% ± 2.0 67.8% ± 2.4	56.3% ± 3.2 56.5% ± 9.0 64.9% ± 1.7
Total Respirable Dose (<5 um) (mg)	Sultanol CromoHEXAL Atrovent	1.49 ± 0.06 11.77 ± 0.44 0.31 ± 0.02	1.23 ± 0.07 10.43 ± 1.87 0.30 ± 0.00
Total Output Rate (TOR) (mg/min)	Sultanol CromoHEXAL Atrovent	0.66 ± 0.03 6.01 ± 0.19 0.15 ± 0.01	0.80 ± 0.14 7.50 ± 1.38 0.16 ± 0.02
Coarse Particle Dose >4.7 microns - %	Sultanol CromoHEXAL Atrovent	37.0 % ±1.2 38.5 % ±2.0 37.2 % ±2.5	49.1 % ±3.1 48.7 % ±8.6 45.4 % ±2.0
Fine Particle Dose <4.7 microns (mg)	Sultanol CromoHEXAL Atrovent	1.40 ± 0.06 10.92 ± 0.43 0.30 ± 0.02	1.13 ± 0.04 9.45 ± 1.78 0.26 ± 0.01
Ultra-Fine Particle Dose <1.0 microns – (mg)	Sultanol CromoHEXAL Atrovent	<LoD	<LoD Limit of Detection

Table 5 – Summary of Comparative Particle Characterization for FOX MOBILE vs. AKITA² APIXNEB (K072019) – Pediatric flow rate – 12 lpm (Confidence interval of 95%)

Particle characterization	Drug	FOX MOBILE	AKITA² APIXNEB (K072019)
MMAD (um)	Sultanol CromoHEXAL Atrovent	3.77 ± 0.09 3.77 ± 0.1 3.68 ± 0.09	4.35 ± 0.28 4.09 ± 0.07 4.31 ± 0.24
GSD	Sultanol CromoHEXAL Atrovent	1.73±0.04 1.58±0.39 1.75±0.02	1.80±0.08 1.74±0.06 1.73±0.10
Emitted Dose (Total Delivered Dose) (mg)	Sultanol CromoHEXAL Atrovent	2.19 ± 0.03 18.15 ± 0.32 0.47 ± 0.01	2.19 ± 0.06 18.51 ± 1.12 0.48 ± 0.01
Total Respirable Dose (< 5 um) (%)	Sultanol CromoHEXAL Atrovent	70.5% ± 1.5 69.1% ± 1.5 71.1% ± 1.7	59.6% ± 6.0 65.8% ± 0.00 56.6% ± 0.00
Total Respirable Dose (0.5 – 5 um) (mg)	Sultanol CromoHEXAL Atrovent	1.53 ± 0.06 12.53 ± 0.40 0.32 ± 0.03	1.30 ± 0.11 12.13 ± 1.20 0.30 ± 0.00
Total Output Rate (TOR) (mg/min)	Sultanol CromoHEXAL Atrovent	0.62 ± 0.02 5.75 ± 0.32 0.14 ± 0.01	0.78 ± 0.18 6.77 ± 0.23 0.17 ± 0.03
Coarse Particle Dose >4.7 microns - %	Sultanol CromoHEXAL Atrovent	33.8 % ±1.6 35.0 % ±1.7 33.0 % ±1.8	45.0 % ±5.8 39.5 % ±2.5 44.8 % ±4.5
Fine Particle Dose <4.7 microns (mg)	Sultanol CromoHEXAL Atrovent	1.45 ± 0.05 11.80 ± 0.42 0.32 ± 0.01	1.20 ± 0.10 11.21 ± 1.13 0.26 ± 0.02
Ultra-Fine Particle Dose <1.0 microns – (mg)	Sultanol CromoHEXAL Atrovent	<LoD	<LoD Limit of Detection

Substantial Equivalence Conclusion -

The sponsor has demonstrated through performance testing, design and features, and non-clinical testing that the proposed device and predicate have been found to be substantially equivalent.