June 24, 2022

Altamira Therapeutics, Inc.
% Patrick Johnson
Regulatory Consultant
DuVal & Associates, P.A.
Medical Arts Building, Suite 1820
825 Nicollet Mall
Minneapolis, Minnesota 55402

Re: K213114
Trade/Device Name: Bentrio™ Allergy Blocker
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: May 24, 2022
Received: May 25, 2022

Dear Patrick Johnson:

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,

Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K213114

Device Name
Bentrio(TM) Allergy Blocker

Indications for Use *(Describe)*
Bentrio is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e., mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hair and dust mites.

Application of Bentrio produces a mucous-like gel barrier that coats the nasal membranes, traps inhaled allergens within the nasal cavity and helps with their clearance.

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 – K213114

Administrative Information

Submitter's Name and Address:

Altamira Therapeutics, Inc.
8 The Green, Ste B
Dover, DE 19901 USA
TEL 302 200 8095
Name of Contact Person: Elena Cavallini, Sr. RA Manager

Date Summary was Prepared: June 24, 2022

Name of Device

Trade or Proprietary Name: Bentrio™ Allergy Blocker
Common or Usual Name: Allergy Blocker Nasal Spray
Classification Name: Cream, Nasal, Topical, Mechanical Allergen Particle Barrier
CFR Reference: 21 CFR 880.5045
Product Code: NUP
Regulatory Class: Class II

Predicate Device

K132520 – Nasal Ease Allergy Blocker, Hi-Tech Pharmacal, Inc.

Product Description

Bentrio™ is a gel emulsion which is applied as a nasal spray for self-protection. It is intended to help protect against allergens such as pollen, house dust, animal hair and dust mites, which are inhaled through your nose and may cause allergic reactions. Bentrio™ is free of any medication such as antihistamines or steroids and does not contain any preservatives.

The gel formulation of Bentrio™ has been designed for extended residence time within the nose. Upon shaking of the spray bottle, it turns liquid which allows for spraying into the nose. After contact with the nasal mucosa, the formulation returns to its gel state and creates the protective barrier. Bentrio™ is cleared from the nasal cavities over time into the throat and eliminated via the digestive tract.

Indications for Use

Bentrio™ is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e., mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hair and dust mites.

Application of Bentrio™ produces a mucous-like gel barrier that coats the nasal membranes, traps inhaled allergens within the nasal cavity and helps with their clearance.

Comparison to Predicate

Parameter	Subject Device	Predicate
	Bentrio™ Allergy Blocker	**Nasal Ease Allergy Blocker K132520**
Indication for Use	Bentrio™ is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust, animal hair and dust mites. Application of Bentrio™ produces a mucous-like gel barrier that coats the nasal membranes, traps inhaled allergens within the nasal cavity and helps with their clearance.	Nasal Ease Allergy Blocker is intended to treat hay fever and allergy sufferers by promoting alleviation of mild allergic symptoms (i.e. mild nasal irritation including itchy, runny, or congested nasal passages) triggered by the inhalation of various airborne allergens including indoor and outdoor environmental pollens, house dust animal hairs and dust mites. Application of Nasal Ease produces a mucous-like gel barrier that evenly coats the nasal membranes and acts to block inhaled allergens within the nasal cavity.
Type of Use (Rx / OTC)	OTC	OTC
User	Adults and children (12 years old and older)	Adults and children (12 years old and older)
Mechanism of Action	Acts to block inhaled allergens within the nasal cavity	Acts to block inhaled allergens within the nasal cavity
User Contact Type	Nasal mucosa	Nasal mucosa
User Interface	Manually activated nasal spray	Manually activated nasal spray
Key design parameters	Thixotropic water-based gel consisting of GRAS inactive ingredients delivered via metered-dose nasal spray	HPMC powder delivered via nasal spray
Sterility	Non-sterile	Non-sterile

Non-Clinical Performance

Safety Testing & Toxicology

Bentrio's ingredients are well characterized and specified for purity and compatibility and are commonly used in medicinal products, cosmetics or in medical devices. The quantity, grade, and route of administration of these ingredients do not present any serious toxicological risks and the quantities administered when used as directed are well below any known recommended daily acceptance levels.

Biocompatibility

Biocompatibility testing included cytotoxicity, acute irritation and sensitization (product formulation excluding vanillin), and irritation and repeated dose acute systemic toxicity of the final product formulation. The results demonstrated that there are no biocompatibility concerns with Bentrio™ for the indicated patient population.

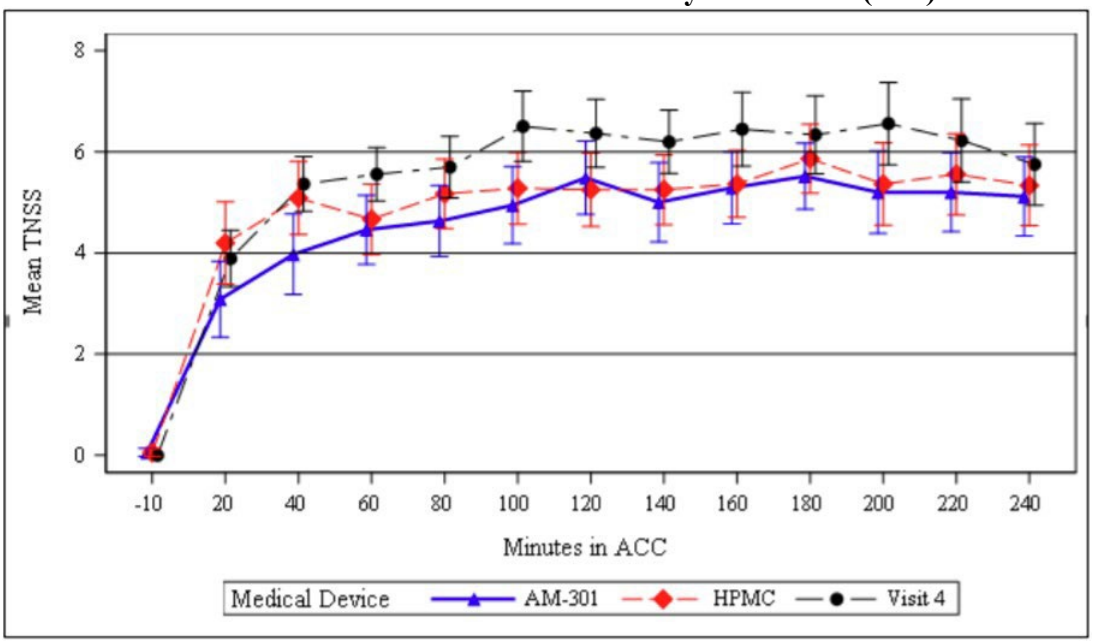
Stability and Shelf Life

Stability and shelf-life testing results support a shelf life of 9 months at 25°C. Once opened, labeling directs the consumer to use the product within 3 months.

Clinical Performance

An open-label, cross-over, randomized, single center clinical study was conducted to demonstrate non-inferiority of Bentrio to the predicate device, Nasal Ease Allergy Blocker, in alleviating the symptoms of allergic rhinitis. Thirty-six study subjects were exposed to pollen in a Fraunhofer Allergen Challenge Chamber (ACC) prior to treatment then randomized and crossed-over after treatment with Bentrio or Nasal Ease. The difference of mean Total Nasal Symptom Score (TNSS) over 240 min during pollen challenge in the ACC (0-240 min) between Bentrio and Nasal Ease supported a conclusion of substantial equivalence for Bentrio relative to Nasal Ease.

Mean TNSS Values for all Time Points by Treatment (ITT)



Extended nasal residence time of Bentrio Allergy Blocker was demonstrated study with fluorescein-stained formulation in 8 healthy volunteers. The formulation remained in the inferior turbinate and septum for up to 240 minutes and in the middle turbinate for up to 90 minutes. Those results are consistent with the protective effects of Bentrio Allergy Blocker observed in the ACC study, which lasted – as for the predicate device – for up to four hours.

Clinical performance of Bentrio Allergy Blocker over two weeks was demonstrated in a multicenter, randomized, open-label, study.

25 subjects with seasonal allergic rhinitis self-administered Bentrio Allergy Blocker or saline nasal spray three times per day or as needed. Treatment with Bentrio Allergy Blocker showed a reduction in the reflective TNSS (worst symptoms over the previous 24 hours) from 6.81

points during Run-in to 4.95 points during the 2-week treatment period. This compares against a reduction from 7.37 to 6.69 points in the saline control group. The reduction was -1.9 points in the Bentrio Allergy Blocker group vs. -0.86 points in the saline control group.
Both treatments were shown to be well-tolerated.

Conclusions

Based on the formulation, intended use, and performance testing, Bentrio^{TM} (K213114) is substantially equivalent to Nasal Ease Allergy Blocker (K132520). Clinical studies have demonstrated that the allergy blocker's mucous-like gel barrier is beneficial to hay fever sufferers through the reduction of nasal allergen exposure and symptoms from seasonal allergic rhinitis.