March 26, 2021

Nasaleze International Ltd
Matt Duxbury
Export Director
Old Castletown Road
Douglas, Isle of Man Im2 1qa
Isle Of Man

Re: K201734
Trade/Device Name: AllerBlock Junior
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical recirculating air cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: February 23, 2021
Received: February 25, 2021

Dear Matt Duxbury:

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
DHT1C: Division of ENT, Sleep Disordered
Breathing, Respiratory and
Anesthesia 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)*
K201734

Device Name
AllerBlock Junior

Indications for Use *(Describe)*
AllerBlock Junior is intended for use in adults and children (8 years or older) 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 AllerBlock Junior 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 *(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

Contact Information

Submitter's Name and Address: Nasaleze International Ltd
Nunnery Mills, Old Castletown Road
Douglas, Isle of Man, IM2 1QA, British Isles
TEL + 44 (0) 1624 611 050

Name of Contact Person: Matt Duxbury, Export Director
Nasaleze International Ltd.

Date Summary was Prepared: March 25, 2021

Name of Device

Name of the Device: AllerBlock Junior
Regulatory Name: Topical Nasal Cream -- Mechanical Allergen Particle Barrier
Regulation 21 CRF 880.5045 / NUP / Class II

Predicate Device

K170848 Alzair Allergy Blocker Cleared 06-14-17

Basis for Submission

1. Expanded the Indications for Use to include pediatric patients (8 years or older).
2. Substituted Strawberry Powder for Mint -- strawberry scent is preferable for children.
3. Updated the product labeling as follows:
   - Includes specific Instructions for children and a new Package Insert
   - Designates that AllerBlock Junior is indicated for Over-the-Counter (OTC) use

Product Description

AllerBlock Junior is composed of pharmaceutical grade Hydroxypropyl Methylcellulose (HPMC; 97%) and high quality strawberry scent (3%) which has been formulated into a micronized powder of fine particles of inert cellulose. AllerBlock Junior is administered by insufflation into the nose using a proprietary spray bottle which enables the powder to be applied evenly as a fine mist to the inside of the nasal cavity.

When the powder comes into contact with the moist surface of the nasal mucosa, it almost immediately forms a colorless, mucus-like fine gel which coats the inside of the nasal cavity. The inert gel acts as a mechanical barrier -- making it more difficult for inhaled allergens to come into contact with the skin in the nasal interior, and thus reducing the intensity of allergic rhinitis (AR) symptoms.

Indications for Use

AllerBlock Junior is intended for use in adults and children (8 years or older) 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 AllerBlock Junior produces a mucous-like gel barrier that evenly coats the nasal membranes and acts to block inhaled allergens within the nasal cavity.

Comparison to Predicate

The table below provides a high level summary of the similarities and differences between the Predicate and Subject products.

	PREDICATE DEVICE	SUBJECT DEVICE
510(K)	K170848	K201734
PRODUCT	Alzair Allergy Blocker	**AllerBlock Junior**
INDICATION	Adult Patients	Adults and **Children (8 years or older)**
INGREDIENTS	HPMC Powder 98.5% Peppermint Powder 1.5%	HPMC Powder 97% **Strawberry Powder 3%**
OTC vs. Rx Use	Rx Use	**OTC**
REGULATION	880.5045 / NUP	SAME

Safety and Performance Testing

Safety Testing and Toxicology	HPMC and strawberry scent flavoring are recognized as GRAS in the US. HPMC is remarkably safe when given orally. The quantity, grade, and route of administration of HPMC used in AllerBlock Junior do not present any serious toxicological risks.
Biocompatibility	Biocompatibility testing included cytotoxicity, sensitization, and irritation. The results demonstrated that there are no biocompatibility concerns with AllerBlock Junior.
Stability / Shelf Life	Stability and shelf life testing results support a shelf life of ≥ 3 yrs at 40°C. Once the bottle is opened, labeling directs the consumer to use the product within 6 months.

Clinical Studies in Children

The safety and effectiveness of AllerBlock Junior (HPMC + Mint) has been clinically investigated in 5 Clinical Studies comprising N=219 pediatric patients as summarized below. The study results are summarized on the next page -- followed by a discussion of the treated patient population, study design, effectiveness and safety results (specific reference to adverse effects and complications), and the basis for determination of substantial equivalence.

	STUDY 1	**STUDY 2**	**STUDY 3**	**STUDY 4**	**STUDY 5**
YEAR	2005	2009	2010	2010	2019
AUTHORS	Aivazis V, Bourli E, Maratou E, Mavroudi A	Zakharzhevskaya T, Sidorenko I, Treskunov V	Aberg N, Dahl A, Benson M	Geppe N, Snegotskaya M, Kolosova N, Konopelko O	Chen X, Guan WJ, Sun SX, Zheng PY, Sun LH, et al
STUDY TITLE	Study of Mucociliary Clearance in Children with AR: Before & After 6 Weeks of Therapy with Natural Cellulose Powder	Efficacy and Safety of Nasaleze in Prevention and Treatment of Persistent AR in Adults and Children	Nasally Applied Cellulose Powder Reduces SAR Symptoms: Double-Blind, Placebo-Controlled Trial in Children & Adolescents	Intranasal Inert Cellulose Powder in Preventing Seasonal Allergic Rhinitis in Children	Effects of Intranasal Cellulose Powder in Children with Allergic Rhinitis -- Randomized-Controlled Trial
TREATMENT	Nasaleze	Nasaleze	Randomized Nasaleze vs. Placebo	Randomized - Nasaleze vs. Standard of Care Oral Meds	Randomized - Nasaleze vs. Nasal Steroids vs. Placebo
DURATION	6 weeks	4 weeks	4 weeks	4 weeks	8 weeks
PT POPULATION	Allergic Rhinitis	Persistent Allergic Rhinitis	History of SAR (in Spring)	Seasonal Allergic Rhinitis	Perennial Allergic Rhinitis
• Total Enrollment	Total Enrollment N=100	Total Enrollment N=48	Total Enrollment N=53	Total Enrollment N=110	Total Enrollment N=121
• Children Treated	**Children Treated N=100**	**Children Treated N=23**	**Children Treated N=25**	**Children Treated N=30**	**Children Treated N=41**
• Age Range + Mean	Ages 1½ - 8 yrs **8 yrs**	Ages 2 - 18 yrs **11 yrs**	Ages 8 - 18 yrs **11 yrs**	Ages 4 - 14 yrs **8 yrs**	Ages 6 - 11 yrs **8 yrs**
PATIENT DEMOGRAPHIC INFORMATION	Male/Female N=53/47 Skin Test Positive N=78/93	Duration of AR 6 yrs (1-15) Skin Test Positive 80% Pollenosis (Hay Fever) 80%	NASALEZE PLACEBO N = 25 N = 28 15/10 M/F 16/12	NASALEZE CONTROLS N = 30 N = 80 3.1 yrs AR 3.8 yrs 50% Skin Test 53% 67% Family 67%	NASALEZE CONTROLS N = 41 N = 80 3.4 yrs AR 3.3 / 3.1 100% Skin Test 100 / 100 71% Family 61 / 76

Clinical Studies in Children (continued)

STUDY 1

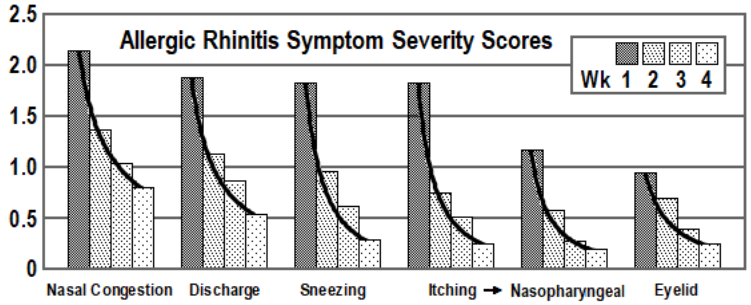
EFFECTIVENESS RESULTS

NASAL MUCOUS CLEARANCE		N	TREATMENT (PRE → POST)	DECREASE
TREATMENT SUCCESS			**95 / 100**	**95%**
Normal Clearance Time	< 24 mins	N = 44	39 → 18 min	54%
Prolonged Clearance Time	> 31 mins	N = 51	55 → 21 min	62%
TREATMENT FAILURE			**5 / 100**	**5%**
Abnormally Prolonged	> 37 mins	N = 5	> 37 min	0

SAFETY RESULTS

- This study demonstrated that Cellulose enhances nasal mucus, which allows the filtration of allergens, to ensure that only clean air reaches the lungs.
- Mucociliary clearance is a first line of defense of ciliated nasal epithelium against inhaled particles such as allergens, pollutants & viruses.
- Improvement in nasal mucous clearance may be attributed to regeneration and normalization of ciliary epithelium.

STUDY 2

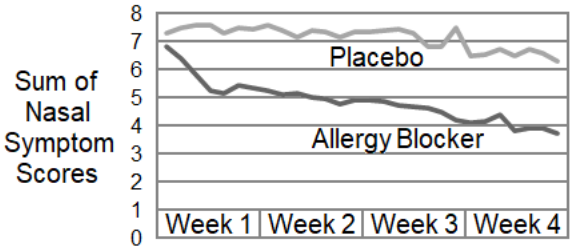


TOLERABILITY	CHILDREN	ADULTS
Very Good	87%	95%
Good	9%	5%
Moderate	4%	---
Poor	---	---

AEs in CHILDREN
- N=1 Itching in nose; sneezing for 1 hr after application
- N=1 Burning in nose

AEs in ADULTS
- N=2 Formation of crusts in nose; first 4 days of therapy
- N=1 Burning in nose

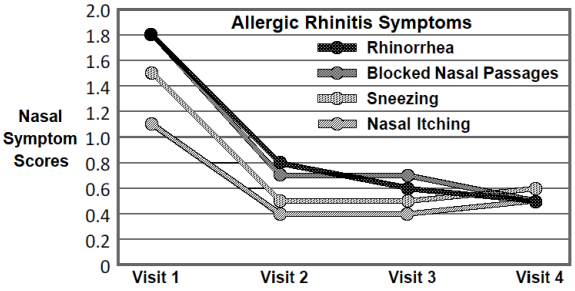
STUDY 3



ADVERSE EFFECTS

No clinically significant adverse effects were reported.
- N=1 Withdrew because of throat irritation
- N=1 Used nasal steroid as rescue medication for 1 day
- N=8 Subjects experienced some nose or throat irritation (N=4 in each group)

STUDY 4



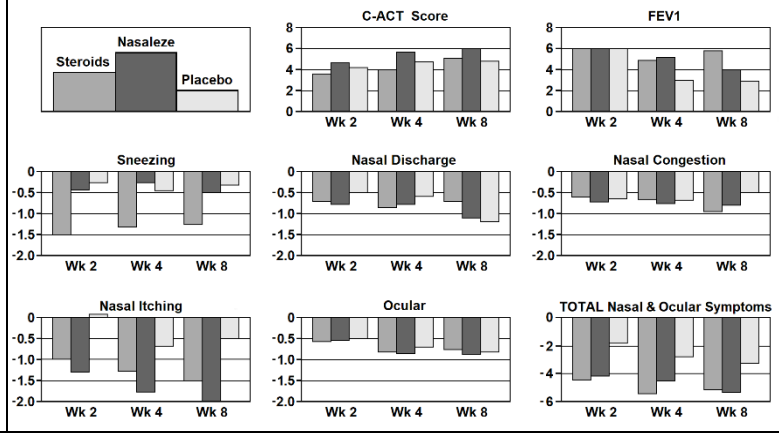
SIDE EFFECTS

The following side effects were reported:

NASALEZE GROUP
- N=2 (7%) Increased sneezing

NASAL STEROID GROUP
- N=2 (7%) Slight nasal bleeding + burning

STUDY 5



Non-serious AEs *		Steroids	Nasaleze	Placebo
Nasal Discomforts **		1	4	5
Epistaxis		1	1	3
Exacerbation	AR	1	2	2
	Asthma	1	1	2
AEs Led to Withdrawal from Study		0	N=1 Epistaxis N=1 Nasal Discomfort	N=1 Epistaxis N=1 Nasal Discomfort

* No Serious Adverse Events (SAEs) were reported.

** Nasal Discomforts -- included nasal itching, sneezing, and nasal stimulation (which was mild and occurred soon after intranasal therapy but resolved spontaneously thereafter).

Clinical Studies in Children (continued)

Discussion

- **Study Design**

  All 5 studies were well-controlled clinical studies in which pediatric patients either acted as their own control (Pre vs. Post-Treatment with AllerBlock Junior) or were randomized to receive AllerBlock Junior vs. Placebo.

- **Treated Patient Population**

  AllerBlock Junior is indicated to treat both adults and children (8 years or older) while the predicate was intended for use in adults only. The specified minimum age of 8 years is based on pooling the age distributions from the 5 clinical studies and observing that approximately half of the patients treated with the Nasaleze product were children 8 years or younger.

- **Effectiveness Results**
  - Study 1 Assessed mucociliary clearance as measure of treatment effectiveness. Significant decrease of clearance observed in children in this study after treatment (especially those with mean value > 31 minutes) is due to the effect of cellulose -- since the children received no other therapy.
  - Study 2-5 Evaluated allergic rhinitis daily symptom scores as reported by subjects. These studies all showed consistent reductions in AR symptoms including nasal congestion and discharge, sneezing, nasal and ocular itching.

- **Safety Results**

  In all 5 studies of children, the reported adverse effects and complications were few in number (2-15%) and mild in level of severity. These results from N=219 pediatric patients treated with AllerBlock Junior demonstrate product safety.

- **Basis for Determination of Substantial Equivalence**
  - **Product Formulation and Ingredients** Strawberry scent flavoring (3%) has been substituted for mint (1.5%):
    - Strawberry scent flavoring is recognized as GRAS in the US
    - Powder particle size remains essentially unchanged

    This change continues to support product safety and effectiveness.
  - **Clinical Equivalence** For the Pediatric Studies, the product investigated was the Allergy Blocker formulation. Since AllerBlock Junior is so similar to Allergy Blocker (see above), this difference does not impact the application of the safety and effectiveness results to support clinical equivalence.

Conclusions

By virtue of its physical characteristics, intended use, and performance testing, AllerBlock Junior is substantially equivalent to Alzair Allergy Blocker. AllerBlock Junior poses no safety risk to users, and has been shown to significantly block allergen entry into the nasal mucosa. Clinical studies of children have demonstrated that AllerBlock Junior's mucous-like gel barrier is beneficial to hay fever sufferers through the reduction of nasal allergen exposure and consequently a reduction in symptoms from seasonal allergic rhinitis.