K120894

MAY 17 2012

The Award Winning, Organic, Natural, Drug-Free, Pollen Barrier
Stop the pollen before it makes you sneeze!
www.haymax.biz

510 (K) Submission — HayMax™ Limited

SUMMARY
SECTION 5

Submitter's Name: HayMax™ Limited
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Date Summary Prepared: 15th March 2012

Name of device
Trade Name: HayMax™Organic Drug-Free Pollen Barrier Balm

Common Name: Pollen Barrier Balm

Classification name: Unclassified

Predicate Devices

510(K)	Manufacturer	Device	Approval Date
KO53625	Turtech Corporation, USA	NasalGuard®	02/22/2006
K042610	Dr Theiss Naturwaren Gmbh, Germany	Dr Theiss Alergol Pollen Blocker Cream	05/16/2005

Vegetarian Society AWARDS 2010

Device description

HayMax™ is a drug free viscous topical nasal balm consisting of a mixture of organic beeswax and organic sunflower oil. There are three further variants: one containing organic freeze dried 200:1 Aloe Vera powder, another containing organic Lavender essential oil and the last containing organic Frankincense essential oil, all in very small quantities.

HayMax™ is used as a pollen blocker prophylaxis for seasonal allergic rhinitis caused by airborne allergens. The product is sparingly applied around the base of the nostrils with a finger, or suitable applicator, eg., cotton swab, where it acts as a mechanical barrier. It traps pollen before it reaches the nasal cavity, thus reducing pollen entering the body. If this maintains the pollen (or other airborne allergen) in a person's body below their sensitivity level then they will not react to the allergen. It is reapplied regularly as required, and after sneezing or blowing the nose. It is intended for topical use and is provided non-sterile. The balm is chemically inert to the body and nasal membranes, and is certified organic.

Intended Use

HayMax™ is intended to promote alleviation of mild allergic symptons, (i.e, mild nasal irritation, including itchy, runny, or congested nasal passages), triggered by the inhalation of various airborne allergens including grass and tree pollen, house dust mite and animal dander. It is intended to be used by anyone who experiences symptoms of hayfever or allergic rhinitis. As it is drug-free and organic it is also considered suitable for children and breast feeding or pregnant women.

Pharmaceutical and Physical Characteristics

HayMax™ Pure (0.17 ounces) contains only certified organic sunflower oil, (helianthus annus), and organic beeswax, (cera flava). The variant, HayMax™ Lavender, (0.17 ounces) also contains a tiny amount of organic lavender essential oil (lavendula angustifolia). The variant, HayMax™ Frankincense (0.17 ounces) also contains a tiny amount of organic frankincense essential oil (Boswellia carterii). The variant HayMax™ Aloe Vera (0.17 ounces) also contains a tiny amount of organic aloe barbadensis leaf juice powder.

All variants have no preservatives and both HayMax™ Pure and HayMax™ Aloe Vera have no odoriferous substances. All ingredients appear on FDA GRAS list.

Summary of technological characteristics of device compared to predicate devices

HayMax™ Pollen Barrier Balm, Alergol Pollen Blocker Cream, and NasalGuard Allergen Blocker Gel are designed to alleviate mild allergic symptoms triggered by the inhalation of various allergens. All are intended for topical use and provided as non-sterile, available in small, similar, (approx 4.6g) quantities and for non prescriptive over the counter use. The application for each requires using finger, (or cotton swab), to wipe product around nasal cavity area, with the purpose of reducing or filtering the amount of inhaled allergens into the nasal interior and thus reducing the intensity of allergic rhinitis symptoms. All products require reapplication at intervals during the day, at non specific times. All products are made from similar substances with similar properties, and although one is called a gel, one a cream, and one a balm they all have similar viscosity and appearance.

These common characteristics indicate that HayMax™ has the same intended use as the predicates. Its substantial similarity to the predicates, the evidence provided by HayMax's own simple trial, (**appendix 2**), the independent research on HayMax™ pollen barrier balm carried out by The National Pollen and Aerobiology Research Unit (NPARU), University of Worcester in July 2009, (**appendix 3**), and January 2012, (**appendix 6**), the testimonials, (**appendix 4**), and the independent tests and reviews, (**appendix 5**), demonstrate that it does not raise new questions of safety and effectiveness and that the device is as effective as the legally marketed devices.

Safety Testing & Shelf Life

By using organic, natural, drug free materials which are found on the GRAS list, HayMax™ is considered an innocuous and safe product. There have been no reports of any serious adverse effects resulting from its use over six years of trading in the UK, with sales approaching one million units.

HayMax™ is registered as a Class 1 Medical Device in the United Kingdom, complying with the requirements of English and European Law (Medical Devices Regulations 2002 and Medical Devices Directive 93/42/EEC respectively).

Stability (**appendix 7**), and safety assessments (**appendix 8**), on HayMax™ carried out by Innovant Research and Innovia International, show that the products are relatively simple blends and contain ingredients that are known to be stable in such formulations. If stored under suitable conditions a best before date of three years from manufacture can typically be applied, and that there are no likely safety hazards from normal use of the product.

Summary Conclusions

By virtue of its physical characteristics and intended use, HayMax™ Pollen Barrier Nasal Balm is substantially equivalent to devices legally cleared to be

marketed in the United States, specifically Dr Theiss Alergol Pollen Blocker Cream and NasalGuard Allergy Blocker Gel.

HayMax™ poses no safety threat or health risk to users and has been demonstrated to trap airborne allergens and work as intended. Because of the physical mode of action of the preparation and its topical administration there are no known interactions with other medicines and it can be safely used complimentary to other forms of treatment for allergic rhinitis.

Verification of Summary

HayMax™ Ltd can verify that the summary includes only information that is also covered in the body of the 510(k). The summary does not contain any puffery or unsubstantiated labeling claims. The summary does not contain any raw data, i.e., contains only summary data. The summary does not contain any trade secret or confidential commercial information. The summary does not contain any patient identification information.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

HayMax™ Ltd
c/o Mr. Max Wiseberg
Managing Director
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United Kingdom, MK45 2EX

MAY 17 2012

Re: K120894
Trade/Device Name: HayMax™ Pollen Barrier Nasal Balms
Regulation Number: 21 CFR 880.5045
Regulation Name: Medical Recirculating Air Cleaner
Regulatory Class: Class II
Product Code: NUP
Dated: March 15, 2012
Received: March 23, 2012

Dear Mr. Wiseberg:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K120894

INDICATIONS FOR USE STATEMENT

(SECTION 4)

Device Name: **HayMax™ Pollen Barrier Nasal Balms**

510(k) Number:

Indications for Use:

HayMax™ organic pollen barrier balm is intended to promote alleviation of mild allergic symptons, (i.e, mild nasal irritation, including itchy, runny, or congested nasal passages), triggered by the inhalation of various airborne allergens including grass and tree pollen, house dust mite and animal dander.

Prescription Use **NO** and/or Over the Counter Use **YES**
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

Over-the-Counter Use X

510(k) Number K120894