K001003

DEC 1 0 2001

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

The following summary is provided pursuant to Section 513(I)(3)(A) of the Federal Food, Drug, and Cosmetic Act.

A. Applicant Information

- ***Submitter:*** Allergy Technology Ltd., Hankerton Field Farm, Crudwell Road, Malmesbury, Wiltshire, United Kingdom
- ***Contact:*** Wharton Shober, D.Sc., Chairman, Telephone: 001-44-1666-577-082, Facsimile: 011-44-1666-577-942, E-mail: Zacharias@btinternet.com
- ***Summary Date:*** March 28, 2000, revised December 3, 2001

B. Device Name and Classification

- ***Proprietary Name:*** Z-Net mattress and pillow covers
- ***Common or Usual Name:*** Allergy control mattress and pillow covers
- ***Classification Name:*** Mattress cover for medical purposes (per 21 CFR § 880.6190)
- ***Predicate Device:*** Allergy Control Covers (K903382) and other mattress covers classified under 21 CFR § 880.6190.

C. Device Description

The Z-Net allergy control device consists of a mattress cover and pillow cover created from polyester impregnated with permethrin. The treated fabric reduces the levels of house dust mites (HDM) and their allergens in the mattress and pillow which, in turn, provides relief to individuals suffering from atopic allergies.

D. Intended Use

Z-Net reduces for up to 15 months house dust mites and their allergens in bedding, a leading cause of allergenic rhinitis, allergenic asthma, and allergenic eczema. Reductions are based on comparisons with untreated bed covers.

E. Comparison to Predicate Device

The primary difference between the Z-Net and Allergy Control covers (and similar mattress covers) relates to the mechanism used by each device to reduce HDM allergens in bedding. The Allergy Control covers protect individuals from exposure to HDM allergens by trapping both the dust mites and the allergens within the covers. The

covers are made of a finely-weaved, semi-permeable fabric, with pore openings significantly smaller than the dust mites or allergens. The device is designed to place between the allergens and the user a barrier through which neither the allergens nor the dust mites can pass. The reduction in exposure is usually short term but can be extended with regular washing of the product.

Rather than placing a barrier between the user and the HDM allergens, the Z-Net covers are treated with permethrin that kills the dust mites and eliminates the production of new allergens. Users are initially exposed to existing allergens, but over time, the allergens break down or migrate away from the mattress and pillow. This provides long term relief from HDM allergens without washing. In addition, whereas the Z-Net mattress cover only covers the top and sides of the mattress, the Allergy Control cover encases the entire mattress, top and bottom. The Z-Net fabric is broadly weaved and is 100 percent polyester. The Allergy Control cover is made of a finely-weaved, semi-permeable, cotton-polyester blend fabric. Finally, the Z-Net is not supposed to be washed, whereas the Allergy Control covers require regular washing.

F. Performance Data

The effectiveness of the Z-Net cover was established primarily through testing conducted at the London School of Hygiene and Tropical Medicine (LSHTM). The two-year, double-blind study was undertaken to determine whether a permethrin-impregnated mattress liner, placed on a mattress without further maintenance, achieved significant long-term reduction of HDMs and their allergens in mattresses. The LSHTM laboratory conducted a pre-intervention analysis of dust samples to confirm that the test and placebo groups were comparable prior to intervention. Dust samples were then collected one month post-intervention, using standardized sampling methods. Thereafter, samples were collected at two months, five months, fifteen months, and twenty-four months. The results of the test confirmed that the use of permethrin-impregnated mattress covers reduces HDMs in bedding. The effectiveness of the Z-Net cover was further established by supplemental documentation relating to the LSHTM study. In addition, many studies were provided demonstrating that a reduction of HDMs in bedding offers relief to sufferers of atopic allergies by reducing their exposure to HDM allergens.

Numerous studies were also submitted to establish the stability of permethrin in fabrics. In particular, reference was made to permethrin's drug master file on file with the Food and Drug Administration (FDA), which establishes the stability of the active ingredient under various storage conditions. Additionally, studies demonstrating the persistence of permethrin in fabrics after rinsing, washing, and exposure to weather and detergent were provided.

The safety of the device was established through direct biocompatability testing of the end product and through reports of various biocompatability reviews of permethrin conducted by the FDA, the Environmental Protection Agency (EPA) and the U.S. Military. The reports confirmed that permethrin has been safely used in topical drug treatments approved by FDA. In addition, EPA has registered technical grades of

permethrin for use in household articles including mattresses and upholstered furniture, as well as in military uniforms – all of which will come into direct contact with the skin. Because permethrin has been used in military uniforms, it has been confirmed as safe by numerous U.S. Military studies. In particular, permethrin is not acutely or subchronically toxic; does not cause skin irritation or sensitization; and is not neurotoxic, immunotoxic, organ toxic, reproductive or developmentally toxic, or carcinogenic. The FDA, EPA, and U.S. Military have all concurred with the general literature in finding permethrin to be safe for use in impregnated fabrics.

G. **Summary**

The safety and effectiveness data submitted to FDA establishes that Z-Net is safe and effective for its intended use and is substantially equivalent to applicable predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 0 2001

Demite Limited
C/O Mr. William H.E. Von Oehsen
Powell. Goldstein, Frazer & Murphy LLP
1001 Pennsylvania Avenue, NW 6th Floor
Washington, District of Columbia 20004

Re: K001003
Trade/Device Name: Z-Net
Regulation Number: 21 CFR 880.6190
Regulation Name: Mattress Cover for Medical Purposes
Regulatory Class: I
Product Code: FMW
Dated: September 21, 2001
Received: September 21, 2001

Dear Mr. Oehsen:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K001003

Device Name: Z-NET

Indications For Use:

Z-Net reduces for up to 15 months house dust mites and their allergens in bedding, a leading cause of allergenic rhinitis, allergenic asthma, and allergenic eczema. Reductions are based on comparisons with untreated bed covers.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K001003