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K 981296

MAY 29 1998

510(k) SUMMARY  
OF SAFETY AND EFFECTIVENESS

This submission covers Geen Medisox, a medical support stocking (21 CFR, 880.5780).

Geen Medisox help prevent pooling of blood in the lower extremities by applying controlled graduated compression starting at 20 mmhg at the ankle and reducing to 8 mmhg at the knee.

Geen Medisox are substantially equivalent to preamendment Jobst stockings (510K numbers listed in Section D of the Premarket Submission Cover Sheet) as they use similar materials, mode of action, and are intended for the same use.

Geen Medisox are knit stockings made from cotton, Lycra, and polyamide, with gradual compression provided by the Lycra. Construction materials are similar to Jobst, and the mode of action for both products is the same. They both provide graduated compression of the lower extremities.

The product being submitted, Geen Medisox, is substantially equivalent to the predicate product in the materials used, mode of action, and indications for use. It has a long history of use and has proven to be as safe and effective as the predicate product.

DATE: March 23, 1998

PREPARED BY: Greg W. Geen  
Geen Healthcare Inc.  
Scarborough, ON  
Canada M1G 3V5



MAY 29 1998

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Greg W. Geen  
President  
Geen Healthcare, Incorporated  
931 Progress Avenue, Unit 13  
Scarborough, Ontario  
CANADA MIG 3V5

Re: K981296  
Trade Name: Geen Medisox  
Regulatory Class: II  
Product Code: DWL  
Dated: April 7, 1998  
Received: April 9, 1998

Dear Mr. Geen:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your pre-market notification submission does not affect any obligation you might have under sections 531 through 542 of

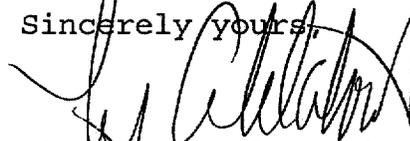
Page 2 - Mr. Geen

the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/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): K981296

DEVICE NAME: GEEN MEDI SOX GRADUATED COMPRESSION SOCKS

INDICATIONS FOR USE:

GEEN MEDI SOX GRADUATED COMPRESSION SOCKS HAVE BEEN DESIGNED TO PREVENT POOLING OF BLOOD IN THE LOWER EXTREMITIES BY APPLYING CONTROLLED GRADUATED COMPRESSION STARTING AT 20 MMHG AT THE ANKLE AND REDUCING TO 8 MMHG AT THE KNEE.

GEEN MEDI SOX HELP IN THE TREATMENT AND PREVENTION OF VARICOSE VEINS, REDUCE THE FEELING OF HEAVINESS AND TIREDNESS IN LEGS, ESPECIALLY FOR THOSE STANDING OR WALKING ALL DAY, AND ALSO HELP TO REDUCE SWELLING IN THE LOWER EXTREMITIES.

DATE: April 30, 1998    PREPARED BY: Greg W. Geen  
Geen Healthcare Inc.  
Scarborough, ON  
Canada M1G 3V5

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter-Use   
(Optional Format 1-2-96)

Patricia Curcillo  
(Division Sign-Off)

Division of Dental, Infection Control,  
and General Hospital Devices

510(k) Number K981296