K013239

Special 510(k): Device Modification Pre-Market Notification

Section G 510(k) Summary

NOV 2 0 2001

Submitters Name .....Paul S. Mitchell, President

Corporate Name.....Med Gen Inc.

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Consulant.....Theodore Barash
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Date of This Summary Preparation ..... September 21, 2001

Trade Name: ComfortCare Compression Support with Magnets
ComfortCare Magnetic Insoles

Common Name..... Elastic Bandage and Medical Insole

Class Under Section 513.....ComfortCare Products Not Classified

Device Description – (a) Elasticized material to support and compress a part of the body. Magnets encased in breathable fabric render comfort. (b) Insole provides magnetic coverage of full foot insole and layered fabric absorbs and vents moisture to keep feet dry.

Intended Use – (a) The compression support line with magnets is designed for the relief of minor discomfort that may have resulted from a simple accident, energetic sports-related or intense workplace activities. Absorption and venting of perspiration keeps targeted anatomical area dry minimizing potential for skin irritation. (b) Magnetic insoles with layered absorptive fabric vents moisture from soles of feet, thereby minimizing damp environment conducive to breeding bacterial and fungal growth.

Technological Character – Among the leading brands, similarities exist in 9 of 11 basic technical characteristics between ComfortCare and legally marketed products. General suppression support marketers (ie Becton-Dickinson and Ace) differ only to the extent that they use neoprene compression and wrap-around elastic fabrics respectively, without the use of magnets. Futuro does not use neoprene. Among dominant marketers with magnets such as Homedics and Nikken, differences exist in their use of neoprene for compression support without fabric absorption properties as compared to ComfortCare. In all cases, however, the intended use, technical attributes and safety of products in this classification, with or without magnets, are essentially the same as ComfortCare products.

Section G 510(k) Summary (continued)

Summary – In the absence of a classification ruling, Med Gen Inc. has referenced similar compression support products and insoles as comparative bases for substantial equivalence.

1) **Such type products are in broad common use in the USA and throughout the world.**

2) **ComfortCare's enhancements do not alter the intended use of 'compression support and insole products' as identified in Section 880.5075 and Section 880.6280 respectively.**

3) **The addition of static magnets at present levels of commercial use, do not present any history of adverse effects as reported by the World Health Organization. Numerous studies, support the safety limits of 20,000 Gauss which have been determined not to produce any detrimental effect on health.**

4) **Magnets have been in use for thousands of years and provide testimony to some level of therapeutic effect that impel its continued life span, placebo effect not withstanding.**

5) **Although the existence of placebo effect has been challenged recently, other studies suggest that placebo effect may be a factor in the same physical response induced by ethical drugs for certain conditions. Some reports indicate that placebo may well represent up to 35% of the desired effect in the administration of certain approved ethical drugs. If magnets work at some placebo level, magnets may be a non-invasive drug-free option for minor discomfort, particularly for 9 of 10 symptoms of the self-limiting variety.**

6) **ComfortCare's modifications do not affect the fundamental technology and science behind similar legally marketed devices.**

7) **ComfortCare's packaging makes no structure/function claims, provides no specific indications and minimally uses magnetic references.**

8) **The copy emphasis on each product's packaging of ComfortCare is on 'compression and support' for ComfortCare's fitments and 'perspiration control' for its insole. Magnets have been de-emphasized.**

9) **The standard that any proposed device be substantially equivalent relies on the premise that any change does not effect or alter the fundamental science and safety of legally marketed devices, the risk posed by the medical device and reasonable equivalency in technological characteristics and, not necessarily identical.**

10) **Given the above, Med Gen Inc. respectfully submits that this application qualifies for classification of its products into Section 880.5075 for Elastic Bandages and Section 880.6280 for medical insoles.**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Theodore Barash
Consultant
Med Gen Incorporated
7284 W. Palmetto Park Road
Boca Raton, Florida 33433-3406

NOV 2 0 2001

Re: K013239
Trade/Device Name: ComfortCare Compression Support with Magnets
ComfortCare Magnetic Insole
Regulation Number: 880.5075 and 880.6280
Regulation Name: Elastic Bandage and Medical Insole
Regulatory Class: I
Product Code: FMQ and KYS
Dated: September 25, 2001
Received: September 28, 2001

Dear Mr. Barash:

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

K013239

NOV 2 0 2001

510(k) Number K013239
Device Name: ComfortCare Compression Support with Magnets. ComfortCare Magnetic Insole

Revision of October 30, 2001

Indications for Use:

ComfortCare Compression Support with Magnets is designed to provide relief of minor physical discomforts that have their origin in stress and strain of repetitive actions associated with athletic, workplace and at-home activities. Device provides support for unprotected vulnerable body parts and post-injury impact induced by overexertion in self-limiting physical injuries.

ComfortCare Absortek fabric construction provides for absorption and venting of perspiration from targeted areas, minimizing potential for skin irritation.

ComfortCare Magnetic Insoles provide foot comfort while layered absorptive fabric vents moisture from feet, minimizing damp environment conducive to breeding bacterial and fungal growth.

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K013239