DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 4 - 2004

Mr. Theodore Barash
Theodore Barash
16879 C Isle of Palms Drive
Delray Beach, Florida 33484

Re: K040054
Trade/Device Name: "Back in Action" Compression & Support with Anti-Bacterial Agent and Magnet
Regulation Number: 880.5075
Regulation Name: Elastic Bandage
Regulatory Class: II
Product Code: FQM
Dated: April 6, 2004
Received: April 7, 2004

Dear Mr. Barash:

This letter corrects our substantially equivalent letter of April 6, 2004 regarding the product code.

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 (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 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.

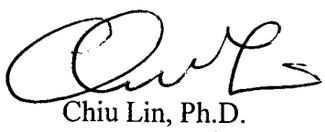
Mr. Barash

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 continue 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 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. Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at their toll free number (800) 638-2041 or at (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K040054

APR 2 7 2004

Section G 510(k) Summary

Submitters Name .....Theodore Barash

Corporate Name Cleared..... ..TheraGen International, Inc.

Address: 16879 C Isle of Palms Dr. Delray Beach, Florida 33484 ..... Ph. 561-498-8926
Fax 561-498-3902
e-mail – tedbarash@aol.com

Written by .....Theodore Barash
561-498-8926

Date of Revised Summary .....April 23, 2004

Trade Name: "Back in Action" Compression and Support with Anti-Bacterial Agent and Magnet

Common Names and Classifications .....

Elastic Bandage Product Code FQM
Predicate 510(k) Number: K013244
Predicate Name: ComfortCare Compression and Support with Anti-Bacterial and Magnet

1.Device Description – (a) Elasticized fitment to support and compress an injured part of the body. (b) Anatomically contoured for adjustable fit and firmness for personal comfort and control of slippage and bunching of fabric. (c) Absortek fiber absorbs perspiration and transfers heat and moisture away from skin (d) Fabric treated with agent to resist growth of odor-causing bacteria and mildew (e) Non-intrusive magnetic panel encased in fabric.

2. Intended Use

For relief of minor physical discomforts occurring by acute trauma, repetitive stress and overuse injuries associated with first degree sprains of overstretched ligaments and first degree strain injuries to tendons. The device compresses, supports and protects vulnerable body parts from post-injury impact incurred by repetitive stress and overexertion self-limiting physical injuries.

K040054

Section G 510(k) Summary (continued)

Technological Character –As indicated in the comparative table in Section E of paragraph 10 on page 10 – the properties of "Back in Action" devices demonstrate the same technological characteristics in design as an elastic bandage, woven fabric, fiber, finish, composition, anti-microbial agent, application, compression/support function, layered absorption/venting mechanisms, magnets and Indications for Use – as granted to ComfortCare products under K 013244, and cleared for marketing in December 07, 2001.

Summary – In addition to claiming substantial equivalence to a predicate under Part 880 Sub Part F -General Hospital and Personal Use Device, Product Code FQM, Regulation # 880.5075 – "Back in Action" products would also qualify for SE under --

Part 890 Subpart F – Physical Medicine Therapeutic Devices, Product Code IOD, Regulation # 890.5350 Exercise Component as "Adjunct to Restore Motion"

Part 890 Sub Part F – Physical Medicine Therapeutic Device, Product Code ILT, Regulation # 890.5050 Daily Activity Assist Device to "Perform an Exercise Function"

1) Products similar to "Back in Action"Compression and Support with Anti-Bacterial and Magnets are in broad common use in the USA and throughout the world.

2) Its characteristics and properties are substantially equivalent to a cleared predicate of 'compression and support products' as identified above.

3) There are no material modifications that affect or change the fundamental technology and science for a similar legally marketed device.

4) The primary copy emphasis of each product's packaging is on multi-tasking attributes of compression, support, perspiration control and anti-microbial protection.

We believe that "Back in Action" products meet the standards for 'substantial equivalence' and merit market clearance by the agency on several levels of application and usage as indicated.

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K 040054

Indications for Use

510(k) Number : K040054
Device Name: "BACK IN ACTION" COMPRESSION & SUPPORT WITH ANTI-BACTERIAL AGENT and MAGNET

Indications For Use:

For relief of minor physical discomforts incurred by acute trauma, repetitive stress and overuse injuries associated with first degree sprains of overstretched ligaments and first degree strain injuries to tendons. The device compresses, supports and protects vulnerable body parts from post-injury impact incurred by repetitive stress and overexertion self-limiting physical injuries.

Prescription Use ____ AND/OR Over-The-Counter Use ___X_____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON OTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number: K040054