K020211

JUN 2 8 2002


**EAST COAST COMPOSITE TECNOLOGIES, LLC**
**1940 OLD DUNBAR RAOD**
**WEST COLUMBIA S.C. 29172**
**PHONE (803) 233-0043**
**FAX (803) 822-8582**


# PREMARKET NOTIFICATION [ 510(K) ]

**Submitted by:**
Randy Sisk

**Completed:**
January 16, 2002

**Device Trade Name:**
BODY FORCE

**COMMON NAME**
BODY TOURNIQUET

**CLASSIFICATION NAME**
COMPRESSIBLE LIMB SLEEVE

# Summary

This will show that the BODY FORCE is equilivant to the Zoex Antishock Trousers [870.5800], in several ways. It will also show a greater life saving benefit.

The BODY FORCE is a composite board, measuring eighteen inches (18") long and eight inches (8") wide and seven-eighths inches (7/8") thick with a loose strap on one side that is two inches (2") wide and seventy inches (70") long. On the other side is a strap that is also two inches (2") wide but only six inches (6") long with a metal ratchet sewn into it. The straps are sewn into a three sixteenth inch (3/16") X four-inch (4") wide stainless steel hinges, with a non-removable pin. The hinges will be held down to the plate by a cam-lock that passes through the board in slots that enable it to be adjusted to several different sizes. There is also a long gated eyebolt that locks into the center of the board that is designed to be used as a bilateral tourniquet for the lower extremities.

The intended use of this device is for all serious crushing injuries of the abdomen and pelvis area. With the signs and symptoms of shock present, and an almost certain death if the object is removed prior to the application of this device. The BODY FORCE can double as a tourniquet to the lower extremities with the eyebolt placed into the center of the board. The long strap is fed over the leg and through the eyebolt and over the other leg into the ratchet and tightened to form a tourniquet. If needed for only one leg, omit the eyebolt and use as if on the abdomen.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 8 2002

Composite Solutions, Inc.
c/o Mr. Randy Sisk
President
1940 Old Dunbar Road
West Columbia, SC 29172

Re: K020211
Trade Name: Body Force, Model BT-6000
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: May 15, 2002
Received: May 17, 2002

Dear Ms. Sisk:

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) 594-4646. 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,

Donna-Bea Tillman, Ph.D.
Acting Director
Division of Cardiovascular
and Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K020211

Device Name: BODY FORCE

Indications for Use:

# STATEMENT OF INDICATIONS FOR USE

## Indications for use

The BODY FORCE is a medical device used on patients who have experienced an abdominal/ pelvic crush injury. The purpose is to prevent a decrease in the central blood volume during transportation to a trauma center.

## Indications for use are: (Tourniquet)

1) Uncontrollable hemorrhaging in the leg(s)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of Cardiovascular
and Respiratory Devices

510(k) Number K020211