K033122

Prizm Medical, Inc.

510(k) SUMMARY of SAFETY and EFFECTIVENESS

I. GENERAL INFORMATION

Trade or (Proprietary) Name:	5000Z System (OTC)
Common or usual name:	Transcutaneous Electronic Nerve Stimulator (TENS)
Classification Name:	FDA has classified Transcutaneous Electronic Nerve Stimulator (TENS) as Class II devices. (21 C.F.R. § 882.5890)
Submitter's Name And Address:	Cathryn N. Cambria for Prizm Medical, Inc. Regulatory Resources Group 5536 Trowbridge Drive Dunwoody, GA 30338
Submission Date:	September 29, 2003

II. INDICATIONS FOR USE

The 5000Z System (OTC) is intended for the symptomatic relief and management of pain in the upper and lower extremities (arms and legs).

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III. DEVICE DESCRIPTION

The 5000Z System (OTC) is a compact battery operated transcutaneous electrical stimulator that delivers a micro-current to the surface area of our patented conductive Silver-Thera E.M. garment electrodes to provide electrical stimulation for pain. It is designed not to exceed 100 volts across the garment electrodes. The technical Specifications for the 5000Z Stimulator can be found in Exhibit E. It is microprocessor controlled, allowing for easy setup of the treatment parameters and precise control of each setting, with a garment electrode dedicated to the upper or lower extremities. The system incorporates a proprietary connection from the stimulator to the electrodes that renders the device unusable without the dedicated electrodes. It is designed for ease of patient use with clearly marked intensity buttons.

Please refer to the Operations Manual (Exhibit A) for photographs and a more thorough description of the device.

The 5000Z System (OTC) is intended for the symptomatic relief and management of pain in the upper and lower extremities (arms and legs).

The primary function of the 5000Z System (OTC) is the same as the Micro-Z™ Stimulation System, Axelgaard Mfg. Co. UltraStim Kit and Woodside Biomedical ReliefBand® and raises no new questions of safety and effectiveness.

JSD

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Prizm Medical, Inc.
c/o Ms. Cathryn N. Cambria
Regulatory Resources Group, Inc.
5536 Trowbridge Drive
Dunwoody, GA 30338

APR 15 2005

Re: K033122
Trade Name: Prizm Medical, Inc. 5000-Z System
Regulatory Name: 21 CFR 882.5890
Regulatory Class: II
Product Code: NUH
Dated: February 10,2005
Received: February 10,2005

Dear Ms. Cambria:

We have reviewed your Section 510(k) preinarket 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). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. 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.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitations must appear in the Warnings section of the device labeling immediately following the indications for use section:

1. Warning: If you have numbness, tingling or loss of feeling/sensation in your arms, hands, legs or feet. this may represent a more serious problem like diabetic neuropathy. Consult your physician before using the device.

2. Warning: If you have swelling of the arm or leg, it may be more serious than simple muscle pain from overuse. Consult your doctor before using the device.

3. Warning: Use the glove or stocking only on healthy skin. Do not use on open wounds or rashes, or over swollen, red, infected or inflamed skin.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device'and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement described above is added to your labeling.

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.

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.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act 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/industry/support/index.html.

Sincerely yours,

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

Enclosure

Indications for Use

510(k) Number (if known): KO?3122

Device Name: P r i m Medical, Inc. 5000

Indications For Use: "To be used for temporary relief of pain associated with sore and aching muscles in the upper and lower extremities (arm and/or leg) due to strain from exercise or normal household and work activities."

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 ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

4/15/05