



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

5/14/98
T-1758M

Dallas District
3310 Live Oak Street
Dallas, Texas 75204-6191

May 6, 1998

Ref: 98-DAL-WL-33

WARNING LETTER

**Via Facsimile and
Federal Express**

Mr. John P. Landino, President
Sterling Medical Technologies, Inc.
801 Jupiter Road, Suite 102
Plano, Texas 75074

Dear Mr. Landino:

We are writing to you because on January 20 through 23 and 30, 1998, an investigator from the Food and Drug Administration (FDA) collected information that revealed a serious regulatory problem involving the products known as Impulse HVG, Perfect Curve II, and Derma-Soft Garment Electrodes which are marketed by your firm.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), this product is considered to be a medical device because it is used to diagnose or treat a medical condition or to affect the structure or function of the body. The law requires that manufacturers of medical devices obtain marketing clearance for their products from FDA before they offer them for sale. This helps protect the public health by ensuring that new medical devices are shown to be either safe and effective or substantially equivalent to other devices already legally marketed in this country.

Our records show that you did not obtain marketing clearance before you began offering the above referenced products for sale when you made significant changes or modification to these devices. Title 21 of the Code of Federal Regulations (21 CFR 807.81(a)(3)) requires a premarket notification for significant changes or modifications to a previously cleared device, including major changes to the intended use the device. The kind of information you need to submit in order to obtain this clearance is described in the enclosed materials. The FDA will evaluate this information and decide whether your product may be legally marketed.

Impulse HVG:

Our records show that the Impulse HVG received marketing clearance under premarket notification, K970847, on September 10, 1997. This clearance allowed this device to be marketed as a powered muscle stimulator for the following intended uses:

1. relaxation of muscle spasm
2. prevention or retardation of disuse atrophy
3. increasing local blood circulation, and
4. maintaining or increasing range of motion

Our review of labeling, promotional material, and a test procedure collected during the inspection revealed that numerous changes or modifications in the intended use of this device have been made. A major change or modification to the intended use of a device requires the submission of a new premarket notification (See 21 CFR 807.81(a)(3)(ii)).

The following uses, found in the documents identified below, are considered major changes or modifications in the intended use of this device which require the submission of a new premarket notification:

1. A promotional piece entitled "The Impulse HVG Rehabilitation System."
 - "post-operative/acute pain"
 - "chronic pain"
2. Instruction manual entitled "Impulse HVG" (page 2).
 - "edema reduction"
 - "reducing motor spasticity"
 - "managing post-traumatic or post-surgical pain conditions"
3. Instruction manual entitled "Impulse HVG" (page 17).
 - "post-operative and acute indications"
 - "pain and swelling"
 - "tissue healing"
 - "Post-operative indications include, but are not limited to the knee, wrist, neck, back and ankle"
 - "Acute indications include, but are not limited to any spinal column or joint related traumas"

4. Instruction manual entitled "Impulse HVG" (page 20)
 - "chronic pain applications"
 - "decreasing pain"
 - "increasing circulation"
 - "improving motor activity"
 - "any possible neurochemical imbalances"
5. Instruction manual entitled "Impulse HVG" (page 21).
 - "edema reduction"
 - "swelling"
 - "post traumatic or recurring edema"
6. Sterling Training Manual
 - "iontophoresis"
 - "denervated nerve and muscle"
 - "Used for open wounds, burns, and over scar tissue"
 - "Can be used over metal implants"
 - "Relieves pain in acute conditions due to reduction of congestion" "Decrease nerve irritability (sedative)"
 - "Produces Ischemia"
 - "Vasodilator"
 - "Relieves pain in chronic conditions due to softening of tissue and increase in circulation"
 - "Increase nerve irritability at low intensity (stimulating)"
 - "Produces Hyperemia"
 - "Hand Injuries: Treating in water is very beneficial. Patients also might report back a looseness feeling especially in the use with arthritic conditions"
 - "Pain: Most conditions associated with pain that respond to TENS can also be treated with HVPGS"
 - "Post Arthroscopy: Becoming more widely used for edema reduction, promotion of wound healing"

"Sprains/Strains: Sports Medicine - very effective at reducing inflammation"

"Edema: The use of ice or positive compression in combination with the HVPGS is suggested. Treatment for edema should be performed in cool water when being used in a bath situation"

"Burns"

"maintenance of muscle integrity (system can influence blood to any area.)
Negative current is a vasodilator"

"TMJ Dysfunction"

"Post surgical wounds: To increase local blood flow, promote tissue granualization, increase fibroblasts and lymphocytes"

"Identification and treatment of trigger points"

"Cervical or lumbar pain"

"Pain associated with arthritis"

"Frozen shoulders"

"Acute and chronic sprains"

"Phantom Limb Pain"

"Cancer Pain"

"WOUND HEALING"

"Edema"

10. Article entitled "Acceleration of Wound Healing with High Voltage, Monophasic, Pulsed Current" from the magazine entitled The Journal of American Physical Therapy Association, Volume 68, No. 4, April 1988.

"wound healing"

11. Article entitled "High Voltage Galvanic Stimulation - An Aid to Post Operative Healing" from the magazine entitled Current Podiatry, May 1981.

"post operative healing"

12. Document entitled TEST PROCEDURE *** IMPULSE HVG.

"post operative pain"

"chronic pain"

"edema reduction"

The above may not be a complete list of major changes or modifications in the intended use of this device requiring the submission of a new premarket notification. You should, therefore, review the claims being made in your labeling, promotional material, and on the Internet to make sure that your device is only promoted for uses for which it is cleared.

Derma-Soft Garment Electrodes:

Our records show that the Derma-Soft Garment Electrodes received marketing clearance under premarket notification, K943009, on February 21, 1995. This clearance allowed this device to be marketed as a cutaneous electrode for the treatment of pain.

Our review of promotional material collected during the inspection revealed that numerous changes or modifications in the intended use of these devices have been made. A major change or modification to the intended use of a device requires the submission of a new premarket notification (See 21 CFR 807.81(a)(3)(ii)).

The following uses, found in the promotional piece entitled "DermaSoft Garment Electrodes," are considered major changes or modifications in the intended use of this device which requires the submission of a new premarket notification:

"therapy for carpal tunnel syndrome"

"arthritic pain"

"RSDS"

"post-operative swelling reduction and pain management"

"diabetic foot pain"

"sprains and fractures in the feet, ankles and other podiatric ailments"

"provides stimulation to the entire foot and ankle to increase blood flow, thereby reducing swelling and associated pain"

"sports injuries"

"repetitive strain disorders"

"post-operative swelling in the knees and elbows"

"therapy for swelling reduction and pain management anywhere at anytime"

The above may not be a complete list of major changes or modifications in the intended use of this device requiring the submission of a new premarket notification. You should, therefore, review the claims being made in your labeling, promotional material, and the Internet to make sure that your device is only promoted for uses for which it is cleared.

Perfect Curve II:

Our records and review show that premarket notification, K891118, which received marketing clearance on September 6, 1989, covers only the Perfect Curve I, and that the Perfect Curve II includes changes and modifications to the Perfect Curve I that could significantly affect safety or effectiveness. Changes which could significantly affect safety or effectiveness require the submission of a new premarket notification (See 21 CFR 807.81(a)(3)(i)).

The following change or modification to the Perfect Curve I could significantly affect safety and requires the submission of a new premarket notification for the Perfect Curve II:

The Perfect Curve I (Sterling TENS), as described in K891118, delivered an electrical signal having a maximum amplitude of 60 milliamperes and a maximum pulse duration of 225 microseconds. This results in a maximum charge per pulse of 13 micro Coulombs. According to the specifications in the labeling, the Perfect Curve II delivers a maximum amplitude of 70 milliamperes, a maximum pulse duration of 450 microseconds which yields a maximum charge per pulse of 32 micro Coulombs.

This change or modification raises new issues of safety because the maximum charge per pulse is over 25 micro Coulombs, and such a charge if applied trans-thoracically may cause cardiac arrhythmia. It is suggested that you contact Mr. Stephen M. Hinckley for advice on submitting a "Special Premarket Notification." Mr. Hinckley may be reached by telephone at (301) 594-1296, extension 164.

Because you do not have marketing clearance from FDA for the significant changes described above, marketing your products is a violation of the law. In legal terms, your products are adulterated under Section 501(f)(1)(B) and misbranded under Section 502(o) of the Act. Your products are adulterated under the Act because you did not obtain premarket approval based on information developed by you that shows your devices are safe and effective. Your products are misbranded under the Act because you did not submit information that shows your devices are substantially equivalent to other devices that are legally marketed.

Our records do not show that a Medical Device Listing Form (FDA-2892) has been submitted for your powered muscle stimulator, transcutaneous electrical nerve stimulators, and cutaneous electrodes. The failure to list these devices, as required by Section 510(j)

of the Federal Food, Drug, and Cosmetic Act (the Act), causes them to be further misbranded within the meaning of Section 502(o) of the Act.

Your devices are also adulterated under Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulations (QSR), as specified in Title 21, Code of Federal Regulations (21 CFR), Part 820, as follows:

1. Failure to establish a complaint handling system, as required by 21 CFR 820.198.
2. Failure to conduct and document device failure investigations, and implement corrective actions were appropriate, as required by 21 CFR 820.100.
3. Failure to establish procedures for, and to conduct and document evaluations of, devices that fail to conform to approved specifications, as required by 21 CFR 820.90.
4. Failure to evaluate and document component supplier ability to meet quality requirements, as required by 21 CFR 820.50(a).
5. Failure to establish procedures for, and document the rework of, nonconforming devices, as required by 21 CFR 820.90(b)(2).
6. Failure to establish and maintain adequate document controls, as required by 21 CFR 820.40. For example, the production testing and assembly procedures contained within the device master records for Simplex and PC TENS devices failed to have management approval signatures.
7. Failure to calibrate inspection, measuring and test equipment, as required by 21 CFR 820.72(a).

You should know that these serious violations of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizing your product inventory, obtaining a court injunction against further marketing of the product, or assessing civil money penalties. Also, other Federal agencies are informed about the warning letters we issue, such as this one, so that they may consider this information when awarding government contracts.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct these problems. We also ask that you explain how you plan to prevent this from happening again. If you need more time, let us know why and when you expect to complete your corrections. Please direct your response to James Austin Templer, Compliance Officer, at the above letterhead address.

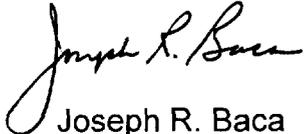
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Sterling Medical Technologies, Inc.

Finally, you should understand that there are many FDA requirements pertaining to the manufacture and marketing of medical devices. This letter pertains to the issues of premarket clearance, device listing and the quality system regulations and does not necessarily address other obligations you have under the law. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at 1-800-638-2041 or through the Internet at <http://www.fda.gov>.

If you have more specific questions about how FDA marketing requirements affect your particular device, or about the content of this letter, please feel free to contact Mr. Templer at the above letterhead address.

Sincerely yours,

A handwritten signature in cursive script that reads "Joseph R. Baca". The signature is written in black ink and is positioned above the printed name and title.

Joseph R. Baca
Dallas District Director