

K965244

AUG 27 1997

Summary of Safety and Effectiveness  
In reference to: 21CFR807.92

Z TECHNOLOGIES, INC.  
2615 Woodacres Rd.  
Atlanta, Ga. 30345-1644  
404-248-0159  
Les Horn

May 23, 1997

Z TECH Model F7 (TENS DEVICE)- Z Technologies, Inc.

The Predicate device is the H-WAVE Model P-4 (TENS DEVICE)-

- Electronic Waveform Labs, Inc.

#20 Safety and effectiveness in accordance with CFR 807.92.

The "Z Tech" TENS Device is technically identical to the "H-Wave" TENS Device, as indicated in the comparison table for the two devices. (SEE EXHIBIT I) The technical characteristics indicated represent the basic output for optimum performance as indicated by "Transcutaneous Neural Stimulation for Relief of Pain"; by Mark Linzer and Doulin M. Long. This article along with the N-S4 article articulates safety standards as well as minimum and maximum levels of output for TENS devices for control of pain. (7 $\mu$ c to 75 $\mu$ c)

The Z Tech Tens Device is designed to produce 0-60 $\mu$ c H-WAVE type pulse which is described as a bi-polar asymmetrical exponentially decaying impulse type waveform. It has a pulse width of approximately 1.5ms and delivers a maximum frequency of 55Hz. These performance characteristics have been shown through clinical experimentation to relieve pain in a significant number of patients in a wide variety of pain states.

Essentially the device originates an astable type pulse of controllable peak voltage, frequency and pulse width, which is amplified and passed to the output electrodes through an isolation transformer, which also eliminates any D.C. component in the output. (Eliminating any D.C. component is a necessary safety feature).

The technological values of charge per phase, charge density, current, voltage, frequency and pulse width, are all controlled and limited to safe levels. These levels are consistent and limited to specifications given and prescribed by clinical testing which is designed to give optimum values for the reduction of pain in human patients.

The device also employs a recharging type circuit which effectively inhibits any patient use during the recharging of permanently installed ni-cad type batteries. Essentially no 110 Volt A.C. component is ever allowed to be present or available to the output of this TENS DEVICE. (Z TECH) The case which is of a lexan plastic type material. Front and rear controls are clearly marked as to their function for ease of patient use.

The device is intended to be used by clinicians in symptomatic relief of chronic intractable pain. Also for post traumatic and post surgical pain relief.

It is most important to note that a large number of patients receiving benefit from TENS type devices are those incapacitated by chronic pain for whom other treatment modalities have failed.

If care is taken by the placement of electrodes, when this device is in use, then an even greater beneficial result will be forthcoming. The device may be used by all type of patients that experience acute and or chronic pain. (especially in areas where other treatments have failed and where drug type therapy is ill advised)

Waveform parameters were recorded using different loading conditions ( $500\Omega$  to  $10k\Omega$ ) for comparison to present and past technology and to the predicate device. These output characteristics and data conform to all safety and effectiveness standards as perscribed by "American National Standard for Transcutaneous Electrical Nerve Stimulators."

The conclusions drawn from clinical and nonclinical tests demonstrate that this TENS type device will effectively relieve patients of chronic and acute pain that otherwise might go untreated. Thus the device may succeed where other types of treatment have been unsuccessful.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 27 1997

Mr. Les W. Horn  
President  
Z Technologies, Inc.  
2615 Woodacres Road  
Atlanta, Georgia 30345-1644

Re: K965244  
Trade Name: Z Tech Transcutaneous Neural Stimulation  
Regulatory Class: II (two)  
Product Code: 84GZJ  
Dated: August 13, 1997  
Received: August 14, 1997

Dear Mr. Horn:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. 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 (Pre-market Approval), 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 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

2 - Mr. Les W. Horn

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Thomas J. Callahan, Ph.D.  
Director  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices  
and Radiological Health

Enclosure

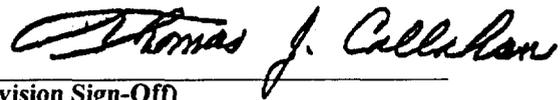
510(k) Number (if known): K965244

Device Name: Z Tech Transcutaneous Neural Stimulation

Indications For Use: The device is intended to be used by clinicians in symptomatic relief of chronic intractable pain. Also, for post traumatic and post surgical pain relief.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)  
Division of Cardiovascular, Respiratory,  
and Neurological Devices  
510(k) Number K965244

Prescription Use X  
(Per 21 CFR 801.109)

OR Over-The-Counter Use \_\_\_\_\_