

H-Wave's 510 (k's)

510(k) Premarket Notification Database	
Device Classification Name	Simulator, Nerve, Transcutaneous, For Pain Relief
510(K) Number	K813601
Regulation Number	882.5890
Device Name	E.W.L. P-TENS MODEL/TENS
Applicant	ELECTRONIC WAVEFORM LABORATORY, INC.
Classification Product Code	Q2J
Date Received	12/28/1981
Decision Date	03/19/1982
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Neurology
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Purged, No Summary Or Statement
Type	Traditional
Reviewed By Third Party	No
K813601	

510(k) Premarket Notification Database	
Device Classification Name	Device, Muscle Monitoring
510(K) Number	K862121
Regulation Number	890.1375
Device Name	E.W.L. P-TENS/H-WAVE
Applicant	ELECTRONIC WAVEFORM LABORATORY, INC. 15583 Chemical Ln. Huntington Beach, CA 92649
Contact	W. J Heeney
Classification Product Code	K2M
Date Received	05/03/1986
Decision Date	06/17/1987
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement/Summary/Purged Status	Purged, No Summary Or Statement
Type	Traditional
Reviewed By Third Party	No
K862121	

510(k) Premarket Notification Database	
Device Classification Name	Device, Electrical Dental Anesthesia
510(K) Number	K873604
Device Name	E.W.L. P-TENS/H-WAVE FOR GENERAL DENTISTRY
Applicant	ELECTRONIC WAVEFORM LABORATORY, INC. 15583 Chemical Ln. Huntington Beach, CA 92649
Contact	William J Heeney
Classification Product Code	L1W
Date Received	09/04/1987
Decision Date	04/12/1988
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Dental
Review Advisory Committee	Dental
Statement/Summary/Purged Status	Purged, No Summary Or Statement
Type	Traditional
Reviewed By Third Party	No
K873604	

510(k) Premarket Notification Database	
Device Classification Name	Stimulator, Muscle, Powered
510(K) Number	K915230
Regulation Number	890.5950
Device Name	H WAVE MUSCLE STIMULATOR
Applicant	ELECTRONIC WAVEFORM LABORATORY, INC. 15583 Chemical Ln. Huntington Beach, CA 92649
Contact	Jim Heeney
Classification Product Code	IEF
Date Received	11/20/1991
Decision Date	05/08/1992
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Physical Medicine
Review Advisory Committee	Neurology
Statement/Summary/Purged Status	Statement/Purged 510(K)
Type	Traditional
Reviewed By Third Party	No
K915230	

Indications for Use

K813601: 1) Chronic intractable pain. 2) Post-operative and traumatic pain

K862121: 1) Muscle spasms associated with TMJ. 2) Muscle re-education, as in regaining joint control in TMJ

K873604: 1) Anesthesia in general dentistry. 2) Amalgams. 3) Composites. 4) Crown preparations. 5) Periodontal Scaling and Root Planing

K915230: 1) Relaxation of muscle spasm. 2) Prevention or retardation of disuse atrophy. 3) Increasing local blood circulation. 4) Muscle re-education. 5) Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis. 6) Maintaining or increasing range of motion

Source: FDA

Is Electrical Stimulation a Proven Medical Treatment?

Yes. In fact, it is one of the most common modality-based procedures ordered by physicians in all of medicine. Furthermore, the related principals are taught in virtually every medical & therapy school in the western world and, there are tens-of-thousands of related articles in the medical and scientific literature. Additionally, it is used, on a daily bases, in literally thousands and thousands of clinical settings and, most, if not all, insurance companies, including MEDICARE, have paid for the related service for more than a quarter of a century.

How does it Work?

Electricity is used to stimulate the patient's muscles and/or nerves. This "stimulus" causes known and predictable physiological and/or neurological responses (i.e. fluid shifts, anesthesia, etc.). It is these known and predictable responses that help physicians treat various medical conditions -- medical conditions that are clearly identified and specifically listed on the FDA's "indications for use" clearance certificate that accompanies every medical device to the marketplace.

For example, if a patient is suffering with "muscle spasms" and/or "chronic intractable pain", and their physician feels that "electrical stimulation" would help, the physician can legally prescribe the use of an FDA cleared powered muscle stimulator (to relax the muscle spasm) and an FDA cleared transcutaneous nerve stimulator (to relieve the pain).

By design, the "indications for use" set by the FDA do not, in any way, restrict use to a specific body part. If a medical device's "indication for use" clearance certificate includes "chronic intractable pain" and "relaxation of a muscle spasm", it does not matter if the pain is in the foot and the spasm is in the hand or vice-a-versa.

Why? Because, when it comes to muscles, nerves, joints and local blood circulation ... the human body's response to electrical stimulation is not site sensitive and, it is safe and effective. Want proof? During the past 25 plus years, the FDA has never found it necessary to significantly amend their "Premarket Notification" process or the related "Indications for Use" clearance certificate that, in effect, governs safety and effectiveness.

This is an extraordinarily important point that, when fully understood, explains why the FDA's "indications for use" clearance certificate for H-Wave's **Powered Muscle Stimulator** reads, "Maintaining or increasing range of motion" not, "Maintaining or increasing range of motion of the left ankle, right knee, right hip, left big toe, etcetera".

As a point of consideration, just imagine what would happen to the entire field of physical medicine and rehabilitation if each of our muscles, nerves and joints operated in an independent and inconsistent manner ... if local blood circulation to our hands was increased by one set of physiological rules and yet another set of rules governed increased local blood circulation to our legs, and yet another set of rules controlled increased local blood circulation to our feet, and so on.

H-Wave[®] ... Potent, Remarkable, Unique & Non-Pharmaceutical

H-Wave is a combination Pain Relief and Powered Muscle Stimulation device ... with some significant twists.

The Pain Relief setting is so potent that it also cleared, by the FDA, for Electrical Dental Anesthesia and related dental procedures. And, the Powered Muscle Stimulator setting is so remarkable that it is also cleared, by the FDA, for regaining joint control in TMJ.

Further, due, in part, to the unique technological characteristics that enable the above, the H-Wave device is able to stimulate rhythmic, non-tetanzing, non-fatiguing muscle contractions (at an ultra low frequency) that help to facilitate localized fluid shifts and there-by enable the circulatory system to more efficiently move nourishment to and waste from the injured area.

This extraordinary operational feature is the primary reason that the majority of H-Wave patients are able to report that, as a direct result of using their H-Wave's, they were able to function with considerably more freedom (increased circulation begets less congestion which begets normalization of function). And, potentially more importantly, that they significantly reduced or eliminated the use of addictive and/or other undesirable injury related drugs.

It is noteworthy to mention that even though traditional electrical stimulation devices (that, by design, cause a tetanzing muscle contraction) are well suited for muscle re-education and muscle toning, they are simply not well suited to produce the type of muscle contraction that will help to facilitate localized fluid shifts.

What's the Difference between H-Wave[®] and TENS?

If we ignore the technological and performance differences and only focus on the FDA's "indications for use"... H-Wave has 15 indications and TENS has two. Both H-Wave and TENS are cleared for "Chronic intractable pain & post operative and traumatic pain" (pain relief setting). But, this is where the similarities end.

Pain Relief Setting

- TENS is designed to provide relief from slight to moderate pain and, it is effective only during use.
- H-Wave is designed to provide relief from levels of pain up to and including those encountered during significant dental procedures and, it is effective both during and after use.

Indications For Use (According to the FDA)	H-Wave	TENS
Chronic intractable pain	YES	YES
Post-operative and traumatic pain	YES	YES
Relaxation of muscle spasm	YES	NO
Maintaining or increasing range-of-motion	YES	NO
Increased local blood circulation	YES	NO
Prevention or retardation of disuse atrophy	YES	NO
Muscle re-education	YES	NO
Immediate post-operative stimulation of calf muscles to prevent venous thrombosis	YES	NO
Muscle spasm associated with TMJ	YES	NO
Muscle re-education, as in regaining control in TMJ	YES	NO
Anesthesia in General Dentistry	YES	NO
Amalgams	YES	NO
Composites	YES	NO
Crown Preparations	YES	NO
Periodontal Scaling and Root Planing	YES	NO

Thus, the "difference" between H-Wave and TENS is that H-Wave's pain relief technology is so potent that it is also cleared by the FDA for Anesthesia in General Dentistry and related dental procedures. And, that TENS offers nothing in regards to addressing the symptoms and clinical issues that nearly always accompany "pain" (see chart above).

What does all this mean? If you are troubled by minor pain (and nothing else) ... TENS is a potentially viable option. If you want a more significant method of pain control and/or a more comprehensive treatment option ... try H-Wave.

Why Do Payers Classify H-Wave[®] as "Durable Medical Equipment, Miscellaneous" E1399?

According to the directions provided by the Healthcare Common Procedure Coding System (HPCPS), the "Durable Medical Equipment, Miscellaneous" code is appropriate if an alternative HPCPS Level II or CPT code does not better describe the service being reported. And, that this code (E1399) should only be used if a more specific code is unavailable.

Since, H-Wave is classified by the Food and Drug Administration's Center for Devices and Radiological Health (FDA) in four separate and distinct categories ... and, there is no code that accurately describes it (H-Wave), there is no other truthful way to code this particular medical device.

Thus, payers are lawfully justified, in fact, compelled, to use the "Durable Medical Equipment, Miscellaneous" code E1399 to describe the H-Wave medical device.

The Guarantee

With H-Wave, post treatment pain relief and increased functionality are not only expected ... the manufacturer provides every patient with a money-back written guarantee.