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510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

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Trade/Proprietary Name: Epix[®] VT TENS System
Classification Name: Transcutaneous Electrical Nerve Stimulator (TENS) per 21 CFR
882.5890
Common/Usual Name: TENS System
Predicate Device: Empi Epix[®] XL TENS System (K881114 and K951503)

Device Description

The Epix[®] VT is a dual channel TENS device with twelve pre-programmed output modes. It is powered by a standard 9V rechargeable battery with a maximum output of 60mA.

The Epix[®] VT has the ability to monitor the pain level of the user before and after a treatment session, number of treatment sessions, the intensity range of each treatment session and the length of each treatment session. Using this information, the Epix[®] VT calculates and displays the percentage of sessions with pain relief, the number of sessions used, the average session length, the most frequent change in pain relief and the most frequent intensity range used.

The Epix[®] VT System requires the use of a set of lead wires and one or two pair of electrodes. The lead wires used with the Epix[®] VT have a protected safety connector which attaches to the device and either a snap or pin style connector which attaches to the electrode.

The currently distributed Empi TENS electrodes require no modification and are compatible for use with the Epix[®] VT System.

Intended Use:

The Epix[®] VT is indicated for the symptomatic relief and management of chronic, intractable pain and adjunctive treatment for post-surgical and post-trauma acute pain. This is identical to the indications for use for the Epix[®] XL.

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS (CONT.)**Comparison of Technological Differences between Equivalent Device and New Device:**

All the critical functional output parameters are the same in the Epix[®] VT and the Epix[®] XL. These parameters are the pulse width, the pulse rate (frequency), the waveform, the amplitude (intensity) range, and power source. The main differences between the devices are related to the user interface. The user controls have been changed from knobs and switches to membrane push buttons and an LCD in the Epix[®] VT. Push buttons are easier to use and control the setting of the adjustable parameters such as amplitude. The output jacks for the lead wire connection in the Epix[®] VT are designed for a safety connector which has no exposed metal to insert into inappropriate outlets such as wall sockets. The Epix VT has 2 frequency options for the Multi-Modulation Mode and 1 frequency option for Modulated Rate Mode. These frequencies are offered in the predicate device along with other frequency options. The Burst mode was also removed due to the similarity between the Ramped Burst and Burst modes. These changes in the output options simplify the choices for determining a comfortable stimulation for the user and do not impact the performance or efficacy of the device. They only limit the number of choices with regard to patient preference. The Epix[®] VT has an added feature of recording and displaying the user's response to treatment. This is accomplished through a 6 point pain scale which turns the device ON or OFF. During a treatment session the device also monitors the session length and intensity range used. This information is accessed through the LCD. These added features do not impact the efficacy or safety of the device.

Assessment of Performance Data**Non-Clinical Test Results**

Design Qualification testing was developed based upon the hazard analysis and available voluntary standards for electromedical devices. The following testing was performed and the results showed that the product meets specifications and functions as expected.

1. Firmware testing
2. Functional testing
3. Simulated Misuse/Safety testing
4. Electromagnetic Immunity and Radiated Emissions testing

Conclusion

The results of all testing done show that this design meets all specifications, is equivalent to currently marketed products and is acceptable for its intended use.