

X 954951

**510(k) Summary of
Safety and Effectiveness**

Manufacturer/ Submitter
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General Device Information

Common/ Usual Name

This device is commonly known as a stimulation electrode.

Trade/ Proprietary Name

Taylor Industries, Inc's trade/ proprietary name for this device is the Taylor TENS (Transcutaneous Electrical Nerve Stimulator) Electrode.

Classification Name(s)

The Taylor TENS Electrode's classification name, classification panel, and regulation citation is:

21 CFR 882.1320

Cutaneous Electrode

84GXY

Device Classification

Similar devices have been determined to be Class II devices according to the Neurological Devices Classification Panel. It is believed that this electrode will be considered to be a Class II device.

Performance Standards

Performance standards (Section 514 of the Act) have not yet been established for the device that is the subject of this premarket notification submission.

Legally Marketed Predicate Device

The Taylor TENS Electrode is substantially equivalent, with similar indications for use to the following devices which are currently legally marketed and in commercial distribution:

*K900519 Classic Medical Products
 Classic ECG/ Stimulating No. 1700 Series Electrode

Device Description

The Taylor TENS Electrode is intended to be used as an ECG or stimulating electrode. The electrode is a Silver/ Silver Chloride conductive coated carbon filled polymer, with an attached leadwire. The adhesive that is being used is a hypo-allergenic hydrogel which allows for an adequate hold to the patient. This product meets all of the applicable AAMI Standards.

Intended Use

The Taylor TENS electrode is designed to be used in monitoring/ stimulating applications. This type of application places the emphasis on the patient's comfort. We recommend that the patient's skin be clean, dry, and shaved, if necessary. It has been shown that a mild abrasion with a prep pad or with fine sandpaper will reduce the inter electrode impedance imbalance, which can cause the pickup of 80 cycle

noise, known as baseline hum. This means that the way a patient's skin is prepared for the electrode, will affect the quality of how the users ECG tracings come out and the performance during stimulation procedures.

The Taylor TENS electrode is for Health Care Professionals only. It is intended for single patient use only.

Conclusion

Comparative testing was done on Taylor TENS electrode and the Classic ECG/ Stimulating No. 1700 Series electrode. Test results indicate that the Taylor TENS electrode provides an equivalent level or better in performance when compared to the legally marketed predicate device when tested to the accuracy requirements as specified in the contents of the premarket notification submission.

Taylor Industries, Inc. feels that the Taylor TENS Electrode is as safe and effective, and performs substantially equivalent to the legally marketed predicate device.