



SEP 5 1996

K962910

510(k) Premarket Notification Amendment to [REDACTED]
Repositionable TENS, NMES, and FES Electrodes

SUMMARY OF SAFETY AND EFFECTIVENESS

Uni-Patch considers their Transcutaneous Electrical Nerve Stimulation (TENS) and Muscle Stimulation (NMES/FES) Electrodes to be as safe and effective as the Axelgaard Manufacturing Company Pals® Plus Reusable Neurostimulation Electrode and the LMI Spec T.E.N.S. Repositionable Pin-Type TENS Electrode (K894042A) with Promeon RG-60 Series gel of which were previously found to be substantially equivalent via a 510(k) Premarket Notification. The safety issues analyzed were skin irritation. The effectiveness of the electrodes was determined by comparing impedance levels.

The first safety issue was to determine if the gel, which is used to adhere the electrode to the skin, would cause any skin irritation. The RG-60 Series gels used in this family of electrodes have passed the required skin sensitivity testing criteria as specified in the Tripartite Biocompatibility Guidance For Medical Devices. These tests include Cytotoxicity, Dermal Sensitization Study (Buehler Patch Test), Repeat Insult Patch Test, and Primary Skin Irritation Test. The gels used in the Uni-Patch TENS and Muscle Stimulation Electrodes have already been used in cutaneous electrodes manufactured by Uni-Patch. Therefore, Uni-Patch considers the RG-60 Series gels used in the manufacturing of their TENS and Muscle Stimulation Electrodes to be acceptable for short-term contact with the skin.

There are no published performance standards for TENS or Muscle Stimulation Electrodes, so Uni-Patch used impedance levels as the criteria for effectiveness testing. When measuring the electrodes impedance, driven at 1K-Hz, we have determined that the electrode impedance values were comparable to all the electrodes tested.

Therefore, Uni-Patch considers its TENS and Muscle Stimulation Electrodes (NMES/FES) to be as safe and effective as the above mentioned TENS/NMES Electrodes.

July 18, 1996

P.O. Box 271 1313 West Grant Blvd. Wabasha, MN 55981-0271
■ 1-800-328-9454 ■ 612-565-2601 ■ Fax 612-565-3971

A **tyco** INTERNATIONAL LTD. COMPANY