

K963236

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**M & R Manufacturing, Inc.  
M&R Disposable Electrodes  
510(k) Summary of Safety and Effectiveness**

The following information is submitted in accordance with the requirements of 21 CFR §807.92:

**Contact Person:** Mark E. Dailey

**Date Prepared:** 12 August 1996

**Proprietary Name:** M&R Disposable Electrodes

**Common/Usual Name:** Disposable electrodes for Transcutaneous Electrical Nerve Stimulation (TENS) and Neuromuscular Nerve Stimulation (NMES).

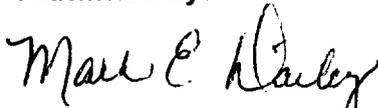
**Classification Name:** Electrodes, cutaneous (84GXY); Class II in accordance with 21 CFR §882.1320.

**Device Description:** M&R Disposable Electrodes are laminated, flexible structures composed of materials commonly used in this application (e.g., cloth with biocompatible adhesive, conductive rubber, and biocompatible conductive gel). The electrodes have a direct lead wire pin connection design and are compatible with all standard, marketed TENS and NMES stimulation devices.

**Intended Use:** M&R Disposable Electrodes are intended for single-patient/single-application use in TENS ("traditional" TENS, microcurrent TENS, etc.) and NMES ("traditional" NMES, interferential NMES, high-volt pulsed galvanic NMES, functional electrical stimulation (FES), etc.) applications.

**Predicate Devices:** Medtronic ComfortEase Disposable TENS and NMES Electrodes, and Medical Designs, Inc. Protector Disposable TENS and NMES Electrodes. A chart comparing characteristics of M&R Disposable Electrodes to the predicate devices, demonstrating substantial equivalence, is attached.

**Submitted by:**



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Device Characteristic	M & R Manufacturing., Inc. M&R Disposable TENS & NMES Electrodes	Medtronic ComfortEase Disposable TENS & NMES Electrodes - K851303	Medical Designs, Inc. Protector Disposable TENS & NMES Electrodes - K911366A
Number of Models	1 model*	3 models	4 models
Electrode Sizes (in.)/ Shapes	2.0 x 2.25 in. (rectangle) * Additional models of various sizes will be added within size range of: 2.0 x 2.0 in. (min.) and 3.0 x 6.0 in. (max.).	1) 2.2 x 2.5 in. (rectangle) 2) 2.0 x 3.5 in. (rectangle) 3) 1.5 x 3.0 in. (butterfly)	1) 2.0 x 2.25 in. (rectangle) 2) 2.0 x 2.75 in. (rectangle) 3) 2.5 x 6.0 in. (rectangle)
Electrode Construction	Polyester w/ biocompatible adhesive Conductive rubber strip Biocompatible gel  * Additional models of the above and following constructions will be added:  1) Polyester w/ biocompatible adhesive Conductive film w/ or w/o Ag/AgCl coating Lead wire assembly Biocompatible gel  2) Polyester w/ biocompatible adhesive Conductive film w/ or w/o Ag/AgCl coating Male snap assembly Biocompatible gel	Polyester w/ biocompatible adhesive Conductive rubber strip Biocompatible gel	1) Polyester w/ biocompatible adhesive Conductive rubber strip Biocompatible gel  2) Polyester w/ biocompatible adhesive Conductive foil Male snap connector Biocompatible gel

<b>Device Characteristic</b>	<b>M &amp; R Manufacturing., Inc. M&amp;R Disposable TENS &amp; NMES Electrodes</b>	<b>Medtronic ComfortEase Disposable TENS &amp; NMES Electrodes - K851303</b>	<b>Medical Designs, Inc. Protector Disposable TENS &amp; NMES Electrodes - K911366A</b>
Lead Wire Connector Type	Std. .080 in. female connection (hole in conductive rubber strip)	Std. .080 in. female connection (hole in conductive rubber strip)	1) Std. .080 in. female connection (hole in conductive rubber strip)  2) Std. wire snap connector
Labeled as Reusable or Single-Use / Disposable?	Single-Use / Disposable	Single-Use / Disposable	Single-Use / Disposable
Indications For Use	TENS & NMES	TENS & NMES	TENS & NMES
Potential adverse effects	Skin irritation	Skin rash	Skin irritation