

FEB - 6 1997

K963125

## **M & R MANUFACTURING**

Telephone 614-694-6511

11967 Upper Fredericktown Amity Rd.  
Fredericktown, OH 43019

**M & R Manufacturing, Inc.  
M&R Reusable 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:** Russell A. Latimer

**Date Prepared:** 30 July 1996

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

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

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

**Device Description:** M&R Reusable Electrodes are laminated, flexible structures composed of materials commonly used in this application (e.g., various cloths, tapes, etc. with biocompatible adhesive, various electrical conductors, and various biocompatible conductive gels). The electrodes are available in models of various sizes with either direct pin lead wire connection or via an integral electrode "prewire" lead wire, and are compatible with all standard, marketed TENS and NMES stimulation devices.

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

**Predicate Device:** Medi-Source, Inc. GeoHesive Reusable Electrodes K903402. A chart comparing characteristics of M&R Reusable Electrodes to the predicate device, demonstrating substantial equivalence, is attached.

**Submitted by:**

*Russell A. Latimer*

Russell A. Latimer  
Secretary & Treasurer  
M & R Manufacturing, Inc.  
11967 Upper Fredericktown Amity Road  
Fredericktown, Ohio 43019  
614/694-6511

**Device Comparison Chart**

<b>Device Characteristic</b>	<b>Medi-Source GeoHesive Reusable Electrodes - K903402</b>	<b>M&amp;R Reusable Electrodes</b>
<b>Number of Models</b>	<b>3 models</b>	<b>37 models</b>
<b>Electrode Sizes (in.)/Shapes</b>  <b>* M&amp;R models 33000 &amp; 35000 are 2-electrode assemblies, each being of the size shown (*).</b>	<ol style="list-style-type: none"> <li>1. 2.000 x 2.000 clover leaf</li> <li>2. 2.000 x 3.000 dog bone</li> <li>3. 2.000 x 6.000 dog bone</li> </ol>	<ol style="list-style-type: none"> <li>1. 1.250 x 1.250 clover leaf</li> <li>2. 1.875 x 1.875 clover leaf</li> <li>3. 2.875 x 1.875 dog bone</li> <li>4. 1.875 x 1.875 square</li> <li>5. 2.000 x 1.250 rectangle</li> <li>6. 1.750 x 1.625 rectangle</li> <li>7. 3.875 x 1.875 rectangle</li> <li>8. 3.875 x 2.500 rectangle *</li> <li>9. 6.000 x 3.875 butterfly</li> <li>10. 1.875 dia. round</li> <li>11. 2.750 dia. round</li> </ol>
<b>Electrode Construction</b>	Vinyl w/ adhesive Lead wire assembly w/ conductive tab Conductive film w/ Ag/AgCl coating Biocompatible gel	<ol style="list-style-type: none"> <li>1. Polyester w/ adhesive Conductive rubber strip Biocompatible gel</li> <li>2. Polyester/polyester film laminate w/ adhesive Conductive rubber strip Biocompatible gel</li> <li>3. Polyethylene foam w/ adhesive Conductive rubber strip Biocompatible gel</li> <li>4. Tricot/polyester laminate Conductive rubber strip Biocompatible gel</li> </ol>

**Device Comparison Chart (cont.)**

<b>Device Characteristic</b>	<b>Medi-Source GeoHesive Reusable Electrodes - K903402</b>	<b>M&amp;R Reusable Electrodes</b>
<b>Electrode Construction (cont.)</b>		<p>5. Polyester film w/adhesive Conductive rubber strip Biocompatible gel</p> <p>6. Polyester w/ adhesive Conductive film Lead wire assembly Biocompatible gel</p> <p>7. Polyester w/ adhesive Conductive film w/ Ag/AgCl coating Lead wire assembly Biocompatible gel</p> <p>8. Polyethylene foam w/ adhesive Conductive film Lead wire assembly Biocompatible gel</p> <p>9. Polyethylene foam w/ adhesive Conductive film w/ Ag/AgCl coating Lead wire assembly Biocompatible gel</p> <p>10. Tricot/polyester laminate w/ adhesive Conductive film Lead wire assembly Biocompatible gel</p>

Device Comparison Chart (cont.)

Device Characteristic	Medi-Source GeoHesive Reusable Electrodes - K903402	M&R Reusable Electrodes
Electrode Construction (cont.)		<p>11. Tricot/polyester laminate w/ adhesive Conductive film w/ Ag/AgCl coating Lead wire assembly Biocompatible gel</p> <p>12. Polyester/polyester film laminate w/ adhesive Conductive film Lead wire assembly Biocompatible gel</p> <p>13. Polyester/polyester film laminate w/ adhesive Conductive film w/ Ag/AgCl coating Lead wire assembly Biocompatible gel</p> <p>14. Polyester film w/ adhesive Conductive film w/ Ag/AgCl coating Lead wire assembly Biocompatible gel</p>
Stimulator Compatibility	Common, marketed TENS & NMES devices	Common, marketed TENS & NMES devices

**Device Comparison Chart (cont.)**

<b>Device Characteristic</b>	<b>Medi-Source GeoHesive Reusable Electrodes - K903402</b>	<b>M&amp;R Reusable Electrodes</b>
<b>Lead Wire Connector Types</b>	Standard .080 in. female connection (built-in electrode lead with connector)	1. Standard .080 in. female connection (built-in electrode lead with connector) 2. Standard .080 in. female connection (hole in conductive rubber strip)
<b>Labeled as reusable or single-use disposable?</b>	Reusable/for single-patient, multiple-application use	Reusable/for single-patient, multiple-application use
<b>Indications For Use</b>	TENS and NMES	TENS and NMES
<b>Stated potential adverse reactions</b>	Skin irritation	Skin irritation