SECTION 6

510(k) Summary

Neurodyn Multiwave

510 (k) Number: K131629

Date of Submission: November 25, 2013

Submitter:

IBRAMED EQUIPAMENTOS MEDICOS
Avenida Dr. Carlos Burgos 2800
Amparo – Sao Paulo – Brasil

TEL – 5519-3817-9633
FAX – 5519-7816-7980

Official Contact:

Lilian Llull
TechLink International Consulting
18851 NE 29th Avenue
Suite 720
Aventura, FL 33180

TEL – (305) 377-0077

This summary is provided in accordance with the Safe Medical Devices Act of 1990 (SMDA). The information provided in the 510 (k) premarket notification is in accordance with 21 CFR 807.87.

Common (Standard) Name: Powered Muscle Stimulator
Trade Name: Neurodyn Multiwave; Aussie Sport

Regulation Number & Product Codes:

GZJ - 21 CFR 882.5890-Transcutaneous electrical nerve stimulator for pain relief
IPF - 21 CFR 890.5850-Powered muscle stimulator
LIH - Interferential Current Therapy-Pre-amendment
GZI- 21 CFR 882.5890-External functional neuromuscular stimulator

Predicate Device Identification:

K121369 Neurodyn/Neurodyn Aussie Powered Muscle Stimulator
K021100 300 PV Complete Electrotherapy
K031077 Vectra Genisys

Predicate devices had been submitted and cleared by 510(k) for the same intended uses and
Device Description

Neurodyn Multiwave and Aussie Sport Neuromuscular Stimulators are intended for the treatment of, relief of chronic (long term) intractable pain as adjunctive treatment of post-surgical and post-traumatic acute pain. Both devices have the same intended uses and incorporate the same technologies as the following predicate devices: Vectra Genisys K031077, Neurodyn/Neurpdun Aussie K121369 and 400PV Complete K021100.

The Neurodyn Multiwave Muscle Stimulator is a programmable device. It comes equipped with 5 preset clinical programs along with 10 user protocols. The user programs are adjustable and can be changed according to the patient’s needs, doctor’s recommendations and prescription settings.

The Aussie Sport Muscle Stimulator has four output channels with independent intensity controls. Thus, four different areas can be stimulated separately or together during a therapy session. It is adjustable and can be changed according to the patient’s needs, doctor’s recommendations and prescription settings. It generates the medium frequency alternate current (MFAC), burst modulated alternating current (Aussie)- type of sinusoidal current with a frequency carrying 1,000 Hz or 4,000 Hz and a burst duration of 4 ms or 2 ms, modulated in pulse trains (bursts) with a variable frequency from 1 to 120Hz.

Indications for Use

Neurodyn Multiwave-Indications for Use:

As a FES device:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient’s gait.

As a TENS device:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post surgical pain

As an Interferential and Premodulated device:
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Russian device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
IBRAMED
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Microcurrent device:
- Symptomatic relief of chronic intractable pain
- Symptomatic relief of post-traumatic acute pain and post surgical pain

As a DC/Polarized device:
- Relaxation of Muscle Spasm

Aussie Sport- Indications for Use:

As an Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

Essential Performance

Neurodyn Multiwave Muscle Stimulator produces the following currents:
Russian/Aussie /Interferential /Tens /Premodulated / Microcurrent/FES/DC Polarized.

The Aussie Sport Muscle Stimulator produces an Aussie current.

Summary of Safety and Effectiveness Conclusion

The Neurodyn Muscle Stimulators are substantially to the predicate devices. All five devices claim similar Indications for Use and Device Characteristics in technological design and materials. The Neurodyn Muscle Stimulators do not raise any new issues of Safety and Effectiveness based on their similarities. The devices have continually proven to be safe and effective and demonstrate intended product performance.

Device Comparison Table

<table>
<thead>
<tr>
<th>Device name</th>
<th>Neurodyn Multiwave</th>
<th>Neurodyn 300 PV Empi</th>
<th>Vectra Genysis</th>
<th>Aussie Sport</th>
<th>Aussie</th>
</tr>
</thead>
<tbody>
<tr>
<td>K Number</td>
<td>K131629</td>
<td>K021100</td>
<td>K031077</td>
<td>K131629</td>
<td>K121369</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Ibramed</td>
<td>Empi</td>
<td>Chattanooga</td>
<td>Ibramed</td>
<td>Ibramed</td>
</tr>
<tr>
<td>Indications for Use</td>
<td>As a FES device: Stimulation of the muscles in the leg and ankle of partially paralyzed patients to</td>
<td>As a FES device: Stimulation of muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot</td>
<td>As a FES device: Stimulation of muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Device Type</td>
<td>Symptomatic Relief</td>
<td>Symptomatic Relief</td>
<td>Symptomatic Relief</td>
<td>Symptomatic Relief</td>
<td></td>
</tr>
<tr>
<td>-----------------------------------</td>
<td>---------------------------------------------------------</td>
<td>---------------------------------------------------------</td>
<td>---------------------------------------------------------</td>
<td>---------------------------------------------------------</td>
<td></td>
</tr>
<tr>
<td>NMES</td>
<td>Retarding or preventing disuse atrophy</td>
<td>Maintaining or increasing range of motion</td>
<td>Reducing muscle spasm</td>
<td>Increasing local blood circulation</td>
<td></td>
</tr>
<tr>
<td>TENS</td>
<td>Symptomatic relief of chronic (long-term)</td>
<td>Symptomatic relief of chronic (long-term)</td>
<td>Symptomatic relief of post-traumatic acute pain</td>
<td>Symptomatic relief of post-traumatic acute pain</td>
<td></td>
</tr>
<tr>
<td>TENS</td>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td></td>
</tr>
<tr>
<td>Interferential and Premodulated</td>
<td>Symptomatic relief of chronic (long-term)</td>
<td>Symptomatic relief of chronic (long-term)</td>
<td>Symptomatic relief of post-traumatic acute pain</td>
<td>Symptomatic relief of post-traumatic acute pain</td>
<td></td>
</tr>
<tr>
<td>DC/Polarized</td>
<td>Relaxation of Muscle Spasm</td>
<td>Relaxation of Muscle Spasm</td>
<td>Relaxation of Muscle Spasm</td>
<td>Relaxation of Muscle Spasm</td>
<td></td>
</tr>
<tr>
<td>Burst Modulated</td>
<td>Temporary relaxation of muscle spasms</td>
<td>Temporary relaxation of muscle spasms</td>
<td>Temporary relaxation of muscle spasms</td>
<td>Temporary relaxation of muscle spasms</td>
<td></td>
</tr>
<tr>
<td>Burst Alternating Russian Current</td>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td></td>
</tr>
<tr>
<td>Burst Modulated</td>
<td>Increase local blood circulation</td>
<td>Increase local blood circulation</td>
<td>Increase local blood circulation</td>
<td>Increase local blood circulation</td>
<td></td>
</tr>
<tr>
<td>Burst Alternating Russian Current</td>
<td>Muscle re-education</td>
<td>Muscle re-education</td>
<td>Muscle re-education</td>
<td>Muscle re-education</td>
<td></td>
</tr>
<tr>
<td>Maintaining or increasing range of motion</td>
<td>Maintaining or increasing range of motion</td>
<td>Maintaining or increasing range of motion</td>
<td>Maintaining or increasing range of motion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>-------------------------------------------</td>
<td>-------------------------------------------</td>
<td>-------------------------------------------</td>
<td>-------------------------------------------</td>
<td></td>
<td></td>
</tr>
<tr>
<td>As an Burst Modulated Alternating Current (Aussie) device:</td>
<td>As a Burst Modulated Alternating Current (Aussie) device:</td>
<td>As a Burst Modulated Alternating Current (Aussie) device:</td>
<td>As an Burst Modulated Alternating Current (Aussie) device:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Temporary relaxation of muscle spasms</td>
<td>Temporary relaxation of muscle spasms</td>
<td>Temporary relaxation of muscle spasms</td>
<td>Temporary relaxation of muscle spasms</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td>Prevention or retardation of disuse atrophy in post-injury type conditions</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Increase local blood circulation</td>
<td>Increase local blood circulation</td>
<td>Increase local blood circulation</td>
<td>Increase local blood circulation</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Muscle re-education</td>
<td>Muscle re-education</td>
<td>Muscle re-education</td>
<td>Muscle re-education</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maintaining or increasing range of motion</td>
<td>Maintaining or increasing range of motion</td>
<td>Maintaining or increasing range of motion</td>
<td>Maintaining or increasing range of motion</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain</td>
<td>Symptomatic relief of chronic intractable pain</td>
<td>Symptomatic relief of chronic intractable pain</td>
<td>Symptomatic relief of chronic intractable pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td>Symptomatic relief of post-traumatic acute pain</td>
<td>Symptomatic relief of post-traumatic acute pain</td>
<td>Symptomatic relief of post-traumatic acute pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>As a Microcurrent device: Symptomatic relief of chronic intractable pain</td>
<td>As a Microcurrent device: Symptomatic relief of chronic intractable pain</td>
<td>As a Microcurrent device: Symptomatic relief of chronic intractable pain</td>
<td>As a Microcurrent device: Symptomatic relief of chronic intractable pain</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td>Symptomatic relief of post-traumatic acute pain and post surgical pain</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Technological characteristics**

**Medium-frequency alternating current (MFAC)**

<table>
<thead>
<tr>
<th>Technology</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
</tr>
</thead>
</table>

<table>
<thead>
<tr>
<th>Device Material</th>
<th>ABS plastic panel LCD display</th>
<th>ABS plastic panel LCD display</th>
<th>ABS plastic panel LCD display</th>
<th>ABS plastic panel LCD display</th>
<th>ABS plastic panel LCD display</th>
<th>ABS plastic panel LCD display</th>
</tr>
</thead>
<tbody>
<tr>
<td>Width (in)</td>
<td>6.8</td>
<td>6.8</td>
<td>9.75</td>
<td>1.26</td>
<td>6.8</td>
<td>6.8</td>
</tr>
<tr>
<td>Height</td>
<td>4.9</td>
<td>4.9</td>
<td>8.75</td>
<td>3.3</td>
<td>4.9</td>
<td>4.9</td>
</tr>
<tr>
<td>Depth</td>
<td>12.4</td>
<td>12.4</td>
<td>12.75</td>
<td>4.5</td>
<td>12.4</td>
<td>12.4</td>
</tr>
<tr>
<td>Number of Channels</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
<td>4</td>
</tr>
<tr>
<td>Temperature range during transport and storage</td>
<td>45°F-110°F</td>
<td>45°F-110°F</td>
<td>-40 to 158°F</td>
<td>-40 to 150°F</td>
<td>45°F-110°F</td>
<td>45°F-110°F</td>
</tr>
<tr>
<td>Environment operating</td>
<td>45°F-110°F</td>
<td>45°F-110°F</td>
<td>50°F to 104°F</td>
<td>45 to 105°F</td>
<td>45°F-110°F</td>
<td>45°F-110°F</td>
</tr>
</tbody>
</table>
# Neurodyn Muscle Stimulators

This premarket notification is being submitted to request clearance for the Neurodyn Muscle Stimulators. The analysis on the device demonstrates substantial equivalence to the Ibramed Neurodyn, Vectra Genisys, and EMPI 300 PV.

## Temperature Range

<table>
<thead>
<tr>
<th>Performance</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
<th>Identical</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocompatibility</td>
<td>FDA cleared</td>
<td>FDA cleared</td>
<td>FDA cleared</td>
<td>FDA cleared</td>
<td>FDA cleared</td>
<td>FDA cleared</td>
</tr>
<tr>
<td>Mechanical Safety</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Anatomical Sites</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
<td>Identical</td>
</tr>
<tr>
<td>Russian</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Aussie</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Interferential</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Microcurrent</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>TENS</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Premodulated</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>FES</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>DC/Polarized</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
<td>No</td>
<td>No</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Voltage Input</th>
<th>100/240V</th>
<th>50/60Hz</th>
<th>100/240V</th>
<th>50/60Hz</th>
<th>3.0V DC</th>
<th>100/240V</th>
<th>50/60Hz</th>
<th>1.0A</th>
<th>100/240V</th>
<th>50/60Hz</th>
<th>1.0A</th>
<th>100/240V</th>
<th>50/60Hz</th>
<th>1.0A</th>
</tr>
</thead>
<tbody>
<tr>
<td>Output</td>
<td>5A+17V</td>
<td>5A+17V</td>
<td>1.0A+3.0V DC</td>
<td>7.3A+24V</td>
<td>5A+17V</td>
<td>5A+17V</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Method of line current isolation</td>
<td>Double Isolation</td>
<td>Double Isolation</td>
<td>Double Isolation</td>
<td>Double Isolation</td>
<td>Double Isolation</td>
<td>Double Isolation</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient leakage control-normal condition</td>
<td>0.0508mA</td>
<td>0.0508mA</td>
<td>0.0502mA</td>
<td>69μA</td>
<td>0.0508mA</td>
<td>0.0508mA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Patient leakage current-single fault condition</td>
<td>0.0252mA</td>
<td>0.0252mA</td>
<td>0.0248mA</td>
<td>31μA</td>
<td>0.0252mA</td>
<td>0.0252mA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Software microprocessor</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automatic overload trip</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Automatic shutoff</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>No</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Locking feature</td>
<td>Keyboard lock safety feature</td>
<td>Keyboard lock safety feature</td>
<td>Keyboard lock safety feature</td>
<td>Keyboard lock safety feature</td>
<td>Keyboard lock safety feature</td>
<td>Keyboard lock safety feature</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Treatment timer</td>
<td>1 to 60 minutes</td>
<td>1 to 60 minutes</td>
<td>5 to 60 minutes</td>
<td>1 to 60 minutes</td>
<td>1 to 60 minutes</td>
<td>1 to 60 minutes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Auto test and repeat</td>
<td>Treatment timer with auto shut off</td>
<td>Treatment timer with auto shut off</td>
<td>Treatment timer with auto shut off</td>
<td>Treatment timer with auto shut off</td>
<td>Treatment timer with auto shut off</td>
<td>Treatment timer with auto shut off</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Frequency Range</td>
<td>.50/60Hz</td>
<td>50/60Hz</td>
<td>---</td>
<td>50/60Hz</td>
<td>50/60Hz</td>
<td>50/60Hz</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Maximum Current Density</td>
<td>2.0 mA</td>
<td>2.0 mA</td>
<td>2.0 mA</td>
<td>2.0 mA</td>
<td>2.0 mA</td>
<td>2.0 mA</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
November 26, 2013

Ibamed Equipamentos Medicos
c/o Ms. Lilian LLull
Techlink International Consulting
18851 NE 29th Avenue Suite 720
Aventura, FL 33180

Re: K131629
Trade/Device Name: Neurodyn Multiwave and Aussie Sport
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ, LIH, GZI
Dated: October 25, 2013
Received: October 28, 2013

Dear Ms. LLull:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical...
device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Joyce M. Whang -S

for Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

510(k) Number (if known): K131629

Device Name: **Neurodyn Multiwave and Aussie Sport**

Indications For Use:

**Neurodyn Multiwave - Indications for Use:**

As a FES device:
- Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

As a TENS device:
- Symptomatic relief of chronic (long term) intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical pain

As an Interferential and Premodulated device:
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Russian device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion

As a Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

As a Microcurrent device:
- Symptomatic relief of chronic intractable pain
- Symptomatic relief of post-traumatic acute pain and post-surgical pain
As a DC/Polarized device:
- Relaxation of Muscle Spasm

**Aussie Sport - Indications for Use:**
As an Burst Modulated Alternating Current (Aussie) device:
- Temporary relaxation of muscle spasms
- Prevention or retardation of disuse atrophy in post-injury type conditions
- Increase local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Symptomatic relief of chronic intractable pain, acute post traumatic pain, or acute post traumatic surgical pain

**Prescription Use **

(Please do not write below this line - continue on another page if needed)

Concurrence of Center for Devices and Radiological Health (CDRH)

Joyce M. Whang -S