



September 12, 2013

Metron Medical Australia Pty Ltd  
c/o David Mitchell, Manager  
Research and Development  
57 Aster Avenue  
Carrum Downs, Victoria 3201  
Australia

Re: K132137

Trade/Device Name: Metron Multi-Stim Model MS-100A  
Regulation Number: 21 CFR 890.5850  
Regulation Name: Powered muscle stimulator  
Regulatory Class: Class II  
Product Code: IPF, GZJ, LIH  
Dated: August 8, 2013  
Received: August 13, 2013

Dear Mr. Mitchell:

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

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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): K132137

Device Name: Metron Multi-Stim Model MS-100A

### Indications For Use:

1. Relief of chronic intractable pain, acute post traumatic pain or acute post surgical pain (Interferential, TNS and Microcurrent waveforms);
2. Relaxation of muscle spasm (all waveforms except Microcurrent);
3. Prevention or retardation of disuse atrophy (all waveforms except Microcurrent);
4. Increasing local blood flow (all waveforms except Microcurrent);
5. Muscle re-education (all waveforms except Microcurrent);
6. Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis (all waveforms except Microcurrent); and
7. Maintaining or increasing range of motion (all waveforms except Microcurrent).

Prescription Use   x    
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF  
NEEDED)

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Concurrence of Center for Devices and Radiological Health (CDRH)

**Joyce M. Whang -S**