



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Redplane AG  
% Mr. Jaen Labuschagne  
Baarerstrasse 8  
Zug,  
Switzerland 6300

**MAY 21 2008**

Re: K070412  
Trade/Device Name: Elexoma Medic  
Regulation Number: 21 CFR 882.5800  
Regulation Name: Cranial Electrotherapy Stimulator  
Regulatory Class: Class III  
Product Code: JXK, GZJ  
Dated: February 6, 2008  
Received: February 21, 2008

Dear Mr. Labuschagne:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or the Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,



Mark N. Melkerson  
Director  
Division of General, Restorative  
and Neurological Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

INDICATION FOR USE STATEMENT FOR CES AND TENS COMPONENTS

510(k) Number (if known): K070412

Device Name: Elexoma Medic

Indication for Use:

The "Elexoma Medic" is a battery operated portable cranial electrotherapy stimulator (CES) device that applies electrical current to a patient's head through electrodes clipped onto the patient's earlobes **to treat insomnia, depression, or anxiety**

and

The "Elexoma Medic" is a battery operated portable transcutaneous electrical nerve stimulator (TENS) device used to apply microcurrent through self-adhesive electrodes to a patient's skin **for the symptomatic relief of intractable pain, chronic intractable pain, post-traumatic and post-surgical pain relief.**

The "Elexoma Medic" is a prescription device according to Federal law.

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use  \_\_\_\_\_ OR Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

Neil K. Dyer for a/c  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number <sup>2-1</sup> K070412