K020803

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JUN 1 0 2002

APPENDIX I. SUMMARY AND CERTIFICATION

APPENDIX I A. 510(K) SUMMARY

Summary of Safety and Effectiveness

In accordance with 21 CFR 807.92, the following information constitutes the CEFAR Medical AB summary for the CEFAR Primo:

SUBMITTER'S NAME:	CEFAR Medical AB
ADDRESS:	Scheelevagen 19F SE-223 70 Lund Sweden
CONTACT PERSON:	Constance Bundy
TELEPHONE NUMBER:	763-574-1976
FAX NUMBER:	763-571-2437
DATE OF SUBMISSION:	11 March 2002

1. **Identification of device**
   Proprietary Name: CEFAR Medical AB CEFAR Primo
   Common Name: Transcutaneous electrical nerve stimulator for pain relief (TENS)
   Classification Status: Class II per regulations 882.5890
   Product Codes: GZJ

2. **Equivalent devices**
   CEFAR Medical AB believes the CEFAR Primo is substantially equivalent to:

TENS-stimulator	SMP-PLUS	Rehabilicare	K982410

3. **Description of the Device**
   The CEFAR Primo is a handheld battery powered TENS device with two channels and nine preset stimulation programs. The two channels are separated and it is possible to stimulate with two different stimulation programs simultaneously, one on each channel.

   Program information and electrical current amplitude is displayed on a LCD. The user can set the amplitude in the range 0-60 mA for all programs.

4. **Intended use**
   The CEFAR Medical AB CEFAR Primo is used for symptomatic relief and management of chronic intractable pain. It is also used as an adjunctive treatment in the management of post-surgical and post-traumatic pain. It has no curative value and should be used only in conjunction with medical supervision.

5. Comparison to predicate device.

Comparison table

Characteristic	SMP-PLUS (Predicate device)	CEFAR Primo
Indications for use statement	Identical	See *Section I B Indications for Use Statement*
Prescription device	Yes	Yes
Number of channels	2	2
Open circuit detection	Yes	Yes
Transcutaneous current delivery	Yes, through electrodes placed on patients body	Yes, through electrodes placed on patients body
LCD dislay	Yes, showing applied intensity in mA and stimulation mode	Yes, showing applied intensity in mA and stimulation program
Power supply	Yes, battery operated 9V	Yes, battery operated 2x1.5 V
Software controlled output	Yes	Yes
Continous stimulation	Yes, user set rate 2-125 Hz and 40-300 µs	Yes, preset 80 Hz and 180 µs, 10 Hz and 180 µs and 80 Hz and 60 µs
Burst	Yes, 8 pulses per burst 2 bursts per second	Yes, 8 pulses per burst 2 bursts per second
Modulated pulse duration	Yes, 60% of set pulse width to users set pulse width 40-300µs	Yes, 70 –180 µs
Mixed frequency	Yes, alternates 60% of set frequency to users set frequency 2-125 Hz every 2.5 seconds	Yes, 2 Hz burst for 3 seconds and 15 Hz or 80 Hz continuous for 3 seconds
User control of output	Yes, push buttons	Yes, push buttons
Pulsed output	Yes, 2-125 Hz	Yes, 2-120 Hz
Pulse form	Asymmetric biphasic, zero net DC	Asymmetric biphasic, zero net DC
Maximum amplitude	60 mA	60 mA
Maximum pulse width	300 µs	180 µs
Maximum charge per pulse	18 µC	10.8µC

6. Discussion of functional and safety testing.

An extensive collection of tests has been conducted and successfully completed, including system validation in-house and external testing to show compliance with IEC EN 60 601-1-2 regarding EMC, IEC EN 60601-1 regarding general safety for medical equipment and IEC EN 60601-2-10 regarding general safety for medical equipment TENS devices.

Notified body SEMKO AB, with ID 0413, has performed the external testing.

7. Conclusion

Based on extensive performance testing and a comparison to the predicate device, it is the conclusion of CEFAR Medical AB that the CEFAR Primo is substantially equivalent to devices already on the marked (cleared by the 510(k) process) and presents no new concerns about safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 1 0 2002

Mrs. Constance G. Bundy
CEFAR Medical AB
C/O: C.G. Bundy and Associates, Inc.
6740 Riverview Terrace
Minneapolis, Minnesota 55432

Re: K020803
Trade/Device Name: CEFAR Primo
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous electrical nerve stimulator for pain relief
Regulatory Class: Class II
Product Code: GZJ
Dated: March 11, 2002
Received: March 12, 2002

Dear Mrs Bundy:

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.

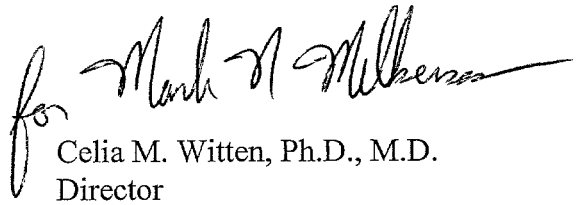
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE

510(k) Number K 020803

Device Name: CEFAR Primo

Indications for Use:

TENS stimulation is used for symptomatic relief and management of chronic intractable pain. It is also used as an adjunctive treatment in the management of post-surgical and post-traumatic pain. It has no curative value and should be used only in conjunction with medical supervision.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over the Counter Use

(Per 21 CFR 801.109)

for Mark N Milhean

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K020803