APR 0 4 2003 K023231

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SUMMARY OF SAFETY AND EFFECTIVENESS

Applicant:

Mediseb Ltd.
6 Galgalei Haplada Str.
Herzelia, ISRAEL 46733
Tel: +972-9-9500885
Fax: +972-9-9500886

Corresponding Official:

Name: Ahava M. Stein, Consultant
Address: A. Stein - Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba
ISRAEL
Tel: +972-9-767 0002
Fax: +972-9-766 8534

Device Name:

Device trade or proprietary name:	**ELF*care*™**, Models 314A, 314B, 314C, 314D, 314E, 314F and 314G
Common Name:	TENS / EMS/ Hot/cold pack
Classification Name:	Transcutaneous Electrical Nerve Stimulation Device, Class II, 882.5890 Powered Muscle Stimulator Device, Class II, 890.5850 Hot/Cold Pack, Class I, 890.5700

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Predicate Devices:

The **ELF***care*™ device is substantially equivalent to a combination of the following devices. Device names', manufacturers and 510(k) numbers are designated in the following table.

Device	Manufacturer	Type of Device	510(k) Number
Vectra PRO 2	Chattanooga Group Inc.	Electrotherapy Device	K982324
Trio 300	ITO CO., Ltd.	Electrotherapy Device	K990787
Thera-Temp Flexible Cold/Hot Packs	Chattanooga group Inc.	Cold Pack	510(k) exempt
Artotherm Cryotherapy and Thermotherapy	Ormed GmbH	Thermal Therapy Device	K913026
TTU-100	Danninger Medical Technology Inc.	Thermal Therapy Device	K964799

Description of the Device:

The **ELF***care*™ device is a lightweight hand held battery operated unit which employs a combination application of previously well known electrical and temperature treatment modalities for pain relief and rehabilitation. The system is based on a combination of thermal transfer and conventional transcutaneous electrical stimulation therapy.

The **ELF***care*™ device makes use of an electronically controlled thermoelectric electrode unit that can be operated in cooling or heating modes. The thermoelectric electrode unit is controlled by the hand-held control unit.

Cooling: In the cooling mode, the thermoelectric electrode unit produces continuous and accurately controlled cold therapy to the treated area.

Heating: When operated in heating mode, well-controlled heat therapy is introduced to the treated area.

Electrotherapy: The unit incorporates a 4-head electrode for localized electrotherapy. Electrical and temperature calibrated modalities are applied in pre-programmed sequences and combinations.

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The **ELF*care***™ device combines electrical and temperature calibrated modalities by means of an electronically controlled thermoelectrode, as described above. The thermoelectrode is placed on the affected area. The thermoelectrode unit is connected to the **ELF*care***™ Control Unit. The treatment programs and treatment parameters are controlled and operated via the **ELF*care***™ Control Unit.

The following table presents the different models of the **ELF*care***™ device that are available:

Features / Model	314A	314B	314C	314D	314E	314F	314G
Electrode Type							
Electro-Thermal Electrode	•	•	•				
Thermal (Hot/Cold)				•	•		
Carbon Electrode (Regular) (not supplied w/ device)						•	•
Electrotherapy Waveforms							
Microcurrent	•	•	•			•	•
IFC (Premodulated Interferential	•	•	•			•	•
VMS Burst	•	•	•			•	•
Russian	•	•	•			•	•
Biphasic Symmetrical Pulses	•	•	•			•	•
Preset Procedures Capability							
16 Programs							•
32 Programs					•	•	
64 Programs			•	•			
128 Programs		•					
256 Programs	•						

General differences between the models:

- The ELFcare™ Models 314A, 314B and 314C use the thermoelectrod. The models varied just by the device memory capabilities as describe in the above table.
- The ELFcare™ Models 314D, 314E are limited to provide only the hot and cold features without electrotherapy capabilities.
- The ELFcare™ Models 314F, 314G are provided without the thermoelectrod. The user can connect standard carbon electrodes using the supplied adaptors.

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Intended Use:

The **ELF***care*™ device Models 314A, 314B, 314C, 314F and 314G is a TENS device intended for the 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.

The **ELF***care*™ device Models 314F and 314G is a EMS device intended for relaxation of muscle spasms, prevention or retardation of disuse atrophy, increasing local blood circulation, muscle re-education, maintaining or increasing range of motion and prevention of venous thrombosis of the calf muscles immediately after surgery.

The **ELF***care*™ device Models 314A, 314B, 314C, 314D, 314E is also a hot/cold therapy device intended for localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions. It is also used to provide temporary relief of minor aches and pains and muscle spasms.

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Performance data:

Safety Testing:

Testing was carried out to assure compliance with recognized electrical safety standards. Mediseb has certified compliance with the IEC 60601-1 standard for electrical safety and compliance with the IEC 60601-1-2 standard for electromagnetic compatibility.

Technological Characteristics Compared to Predicate Device

The technological characteristics, e.g., overall design, materials, mechanism of action, mode of operation, performance characteristics, etc., and the intended use of the ELFcare™ device are substantially equivalent to the predicate devices cited above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 0 4 2003

Mediseb Ltd.
c/o Ms. Ahava M. Stein
Regulatory Affairs Consulting
Beit Hapa'amon (Box 124)
20 Hata'as St.
44425 Kfar Saba, ISRAEL

Re: K023231
Trade/Device Name: The ELF*care*™, Models 314A, 314B, 314C, 314F and 314G
The ELF*care*™, Models 314F and 314G
The ELF*care*™, Models 314A, 314B, 314C, 314D and 314E
Regulation Numbers: 21 CFR 882.5890, 21 CFR 890.5850, 21 CFR 890.5720
Regulation Names: Transcutaneous electrical nerve stimulator for pain relief
Powered muscle stimulator
Water circulating hot or cold pack
Regulatory Class: Class II
Product Codes: GZJ, IPF, ILO
Dated: December 23, 2002
Received: January 6, 2003

Dear Ms. Stein:

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.

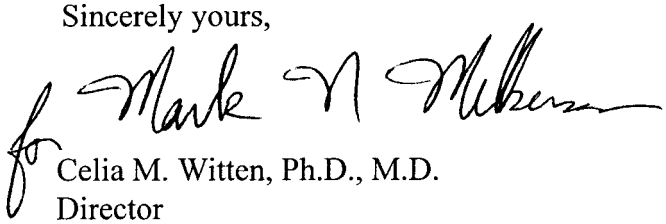
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (301) 594-4659. 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) you may obtain. 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,



for 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

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INDICATIONS FOR USE STATEMENT

510(k) Number: K023231

Device Name: ELF*care*™, Models: 314A, 314B, 314C, 314D, 314E, 314F and 314G

Indications for use:

For Microcurrent and IFC (Premodulated Interferential) electrical stimulation using models 314A, 314B, 314C, 314F and 314G:

- Symptomatic relief and management of chronic intractable pain
- Adjunctive treatment in the management of post-surgical and post-traumatic pain.

For VMS Burst, Russian and Biphasic Symmetrical Pulses electrical stimulation using models 314F and 314G:

- Relaxation of muscle spasms
- Prevention or retardation of disuse atrophy
- Increasing local blood circulation
- Muscle re-education
- Maintaining or increasing range of motion
- Prevention of venous thrombosis of the calf muscles immediately after surgery

For Hot/Cold therapy using models: 314A, 314B, 314C, 314D, 314E:

- Localized thermal therapy (hot or cold) for post traumatic and post surgical medical and/or surgical conditions.
- Temporary relief of minor aches and pains and muscle spasms

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X (Per 21 C.F.R. 801.109) OR Over-The-Counter Use _____ (Optional Format 1-2-96)

for Mark N. Melkerson

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

510(k) Number K023231