Закрытое акционерное общество "ОКБ "РИТМ"
RITM OKB ZAO

JUL 1 1 2014

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K131513

510(k) Summary

Submitter Information:
RITM OKB ZAO
Address: 99, Petrovskaya str., Taganrog, Russia, 347900
Phone/fax: +7 (8634) 623-179
Contact person: Larisa Shpungina
Date of Summary Preparation: May 19, 2014

Trade Name:
SCENAR (SCELAP, ENISAR, IPENS) Cutaneous Electrode Family

Common Name:
Transcutaneous Electrical Nerve Stimulator

Classification Name:
TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR (21 CFR 882.5890, PRODUCT CODE GZJ)

Predicate Device:
SCENAR (K092117)
InterX5000 (K042912)

Description:
The SCENAR Cutaneous Electrode Family is intended to be used with electrostimulation devices produced by RITM OKB ZAO as external add-on electrode accessories.

Purpose
Purpose of SCENAR transcutaneous electrostimulator (K092117) is completely specified. SCENAR transcutaneous electrostimulators and SCENAR Cutaneous Electrode Family are designed for delivering general non-invasive treatment via human skin areas for relief and management of chronic and acute pain, as adjunctive treatment in the management of post-surgical and post-traumatic pain.

SCENAR devices and SCENAR Cutaneous Electrode Family can be used:
– at home on a doctor's prescription to relief pain after various injuries and traumas;
– by medical professionals in medical and prophylactic institutions – as an independent remedy as well as combined with other treatments.

Action: How it works
SCENAR devices generate low and medium frequency bipolar electric pulses. The shape of the pulses dynamically varies with changing electrophysiological characteristics of the skin. The SCENAR Cutaneous Electrode Family has no power unless it is connected to transcutaneous electrostimulator. The SCENAR Cutaneous Electrode Family is placed

directly onto unbroken skin and does not use any conductive gels. These electrodes serve as complement to the device and allow influencing the special or hard-to-get-to parts of the body in comparison with built-in electrode.
The **small** electrode facilitates to influence parts with difficult relief –ulnar and wrist joints, feet etc. and also while using in pediatrics.
The **comb** electrode facilitates to influence pubis, axilla and other hairy parts of the skin.
The **point** electrode allows carrying out condensed influence to reflexogenic points of extremities and ears.

List of produced devices
The SCENAR Cutaneous Electrode Family produced by RITM OKB ZAO is listed in the Table 1. The Electrodes are united into array since their purpose, application, mechanism of action, utilized materials, basic technical characteristics, functionality and manufacturing processes are similar.

Table 1

Electrode Model
Small electrode
Comb electrode
Point electrode

Specifications
Specifications of SCENAR Cutaneous Electrode Family are given in Table 2.

Table 2

Parameter	Small electrode	Comb electrode	Point electrode
Type of electrodes	coaxial bipolar	multipoint bipolar	coaxial bipolar
Dimensions (without cable)	not more than 50x40x25 mm	not more than 60x40x25 mm	not more than ∅15x120 mm
Weight (whole electrode)	not more than 0.04 kg	not more than 0.05 kg	not more than 0.04 kg
Cable length	(900 ± 100) mm		

Design Description
The SCENAR Cutaneous Electrode Family does not contain any electrical components. Electrodes are made of stainless steel, brass with silver plated, ABS plastic and fluoroplastic placed in ABS plastic case. The electrodes are connected to electrostimulator by wiring through a connector cable.
The cable is a two conductor cable using two single wires tinned with copper.
The connector is medically recognized and cannot be plugged into an AC socket.

Materials
Stainless steel, brass with silver plated, ABS, fluoroplastic – electrodes, ABS – case.

Power supply
The SCENAR Cutaneous Electrode Family does not contain power supply.

Sterilization
The SCENAR Cutaneous Electrode Family is intended to be used non-sterile.

Software
The SCENAR Cutaneous Electrode Family does not contain any software/firmware.

Indications for Use
The SCENAR Cutaneous Electrode Family with SCENAR TENS devices is indicated for relief and management of chronic and acute pain, as adjunctive treatment in the management of post-surgical and post-traumatic pain.

Substantial Equivalence Comparison
The performance comparison of SCENAR Cutaneous Electrode Family and INTERX5000 optional external electrode accessories is given in Table 3.
Performance testing was conducted to characterize the performance of the SCENAR Cutaneous Electrode Family as compared to published data of predicate devices InterX5000 optional external electrode accessories.

Table 3

Parameter	SCENAR Cutaneous Electrode Family	InterX5000 optional external electrode accessories
Type of electrodes	small – coaxial bipolar comb – multipoint bipolar point – coaxial bipolar	classic – coaxial bipolar comb – multipoint bipolar small circular – coaxial bipolar
Dimensions (without cable)	small – 45x37x22 mm comb – 55x37x22 mm point – Ø11x117 mm	classic – ~ 80x40x20 mm comb – ~ 80x40x20 mm small circular – ~ Ø16x130 mm
Weight (whole electrode)	small – 0.028 kg comb – 0.040 kg point – 0.022 kg	data not available
Cable length	small – 910 mm comb – 905 mm point – 907 mm	data not available

The differences in dimensions of the subject and predicate devices are minor because:
– the dimensions of the electrode's part contacting the skin differ unsignificantly (2-5 mm). These dimensions are approximately determined by the purpose of the electrode and their minor deviations do not affect the Indications for Use and Fundamental scientific technology of the proposed electrodes;
– the third dimension (length) of the electrode has been determined considering ergonomics. This dimension as well as the shape of the electrode body can influence only the comfort of performing manipulations with the electrode, and maybe, the way the electrode is held.

SCENAR Cutaneous Electrode Family complies with performance standard requirements (21 CFR 898.12) relating to patient lead wires and electrodes.
RITM OKB ZAO has received test reports certifying that SCENAR Cutaneous Electrode Family was tested and found to be in conformity with IEC 60601-1, IEC 60601-2-10 and IEC 60601-1-2 international safety and EMC standards.
The test reports have been provided as part of this premarket notification. Test results of SCENAR devices with add-on electrodes (SCENAR Cutaneous Electrode Family) are given in the test reports.

Conclusions
The devices have intended use and technological characteristics that are substantially equivalent to those of the predicate device InterX5000 (K042912) (optional external electrode accessories) and SCENAR (K092117).
The test reports contained in this submission demonstrate that the submitted models are equivalent to the safety and effectiveness as that of the cleared devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2014

Ritm Okb Zao
Larisa Shpungina
Certification and Licensing Engineer
99, Petrovskaya Str., Taganrog,
347900, Russia

Re: K131513
Trade/Device Name: SCENAR Cutaneous Electrode Family
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator
Regulatory Class: Class II
Product Code: GZJ, GXY
Dated: May 19, 2014
Received: June 11, 2014

Dear Ms. Shpungina:

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 Industry and Consumer Education 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" (21CFR 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 Industry and Consumer Education 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,

Felipe Aguel -S

for Carlos L. Peña, PhD, MS
Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K131513

Device Name
SCENAR (SCELAP, ENISAR, IPENS) Cutaneous Electrode Family

Indications for Use *(Describe)*
The SCENAR Cutaneous Electrode Family with SCENAR TENS devices is indicated for relief and management of chronic and acute pain, as adjunctive treatment in the management of post-surgical and post-traumatic pain.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Felipe Aguel -S Date: 2014.07.11 11:51:26 -04'00'

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