

**Закрытое акционерное общество "ОКБ "РИТМ"
RITM OKB ZAO**

MAY 28 2010

ЗАО "ОКБ "РИТМ",
ул.Петровская, 99,
г.Таганрог, Россия, 347900
Тел./факс: (8634) 62-31-79
E-mail: medsc@scenar.com.ru

RITM OKB ZAO
Petrovskaya St., 99
Taganrog, Russia, 347900
Tel./fax: (8634) 62-31-79
E-mail: medsc@scenar.com.ru

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: November 11, 2009

Trade Name:

SCENAR

Common Name:

TENS device

Classification Name:

TRANSCUTANEOUS ELECTRICAL NERVE STIMULATOR FOR PAIN RELIEF (21
CFR 882.5890, Product Code GZJ)

Predicate Device:

InterX5000 (K042912)

Device Description:***Purpose***

SCENAR transcutaneous electrostimulators 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 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.

List of produced devices

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

Table 1

Device Model and Version
SCENAR-1-NT (version 02) – Transcutaneous electrostimulator.
CHANS-01-SCENAR – Transcutaneous electrostimulator.
CHANS-01-SCENAR-M – Transcutaneous electrostimulator.

Specifications

Specifications of SCENAR devices are given in Table 2.

Table 2

Parameter	SCENAR-1-NT (version 02)	CHANS-01-SCENAR CHANS-01-SCENAR-M
Supply voltage	4.0 to 6.4 V	9 V
Maximum supply current	not more than 650 mA	not more than 85 mA
Amplitude of the stimulating pulse at a standard load	not more than 150 V	not more than 150 V
Pulse frequency	15 to 350 Hz	14, 60, 90, 340 Hz
Pulse Width	7 – 2000 μ S	7 – 1000 μ S
Maximum Output RMS Voltage	12 V @ 500 Ω	15 V @ 500 Ω
	15 V @ 2 k Ω	20 V @ 2 k Ω
	15 V @ 10 k Ω	20 V @ 10 k Ω
Maximum Output RMS Current	25 mA @ 500 Ω	30 mA @ 500 Ω
	8 mA @ 2 k Ω	10 mA @ 2 k Ω
	1.5 mA @ 10 k Ω	2 mA @ 10 k Ω
Weight	not more than 0.4 kg	not more than 0.2 kg
Dimensions	not more than 190x70x40 mm	not more than 140x55x35 mm

Design Description

The device has an upper cover, case with a built-in electrode and a battery cover. All components except for the batteries are located on the printed circuit board inside the device's case. The device's controls and visual indicators are located on the upper side of its case.

Materials

Stainless steel – electrode, ABS – case.

Power supply

Alkaline batteries.

Intended Use

SCENAR is indicated for:

- relief and management of chronic and acute pain
- adjunctive treatment in the management of post-surgical and post-traumatic pain.

The comparison of SCENAR and INTERX5000 Specifications is given in Table 3.

Table 3

Parameter	SCENAR	InterX5000
Supply voltage	CHANS-01-SCENAR, CHANS-01-SCENAR-M – 9 V SCENAR-1-NT (versions 02) – 4.0 to 6.4 V	9 V
Maximum supply current	CHANS-01-SCENAR, CHANS-01-SCENAR-M – not more than 85 mA SCENAR-1-NT (versions 02) – not more than 650 mA	data not available
Amplitude of the stimulating pulse at a standard load	not more than 150 V	not more than 450 V (measuring conditions not available)
Pulse frequency	CHANS-01-SCENAR, CHANS-01-SCENAR-M – 14, 60, 90, 340 Hz SCENAR-1-NT (version 02) – 15 to 350 Hz	15 to 350 Hz
Weight	CHANS-01-SCENAR, CHANS-01-SCENAR-M – not more than 0.2 kg SCENAR-1-NT (versions 02) – not more than 0.4 kg	not more than 0.3 kg
Dimensions	CHANS-01-SCENAR, CHANS-01-SCENAR-M – not more than 140x55x35 mm SCENAR-1-NT (versions 02) – not more than 190x70x40 mm	220x60x45 mm

Moreover, to support our determination of substantial equivalence, evaluation tests have been performed. The results of these tests demonstrate that technological characteristics and performance of SCENAR devices are substantially equivalent to those of InterX5000. The test reports have been provided as part of this premarket notification.

The software verification has been conducted according to the Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices - Guidance for Industry and FDA Staff- May 11, 2005.

RITM OKB ZAO has received test reports certifying that SCENAR was tested and found to be in conformity with IEC 60601-2-10:2001 + A1:2001 and IEC 60601-1:1988 + A1:1991 + A2:1995 and EMC: IEC 60601-1-2:2001 (ed. 2) international safety standards.

The test reports have been provided as part of this premarket notification.

SCENAR has received the CE Mark in the category *Impulse Therapy devices type SCENAR* for the devices in this submission certifying that the devices meet the EC-Directive 93/42/EEC.

The Certificate has been provided as part of this premarket notification.

Conclusions

The devices have intended uses and technological characteristics that are substantially equivalent to those of the predicate device InterX5000 (K042912).

Verification and validation tests as well as certificates and 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

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

RITM OKB ZAO
c/o Ms. Larisa Shpungina
Certification and Licensing Engineer
99 Petrovskaya str.,
Taganrog, 347900
Russia

Re: K092117

MAY 28 2010

Trade Name(s): CHANS-01-SCENAR,
CHANS-01-SCENAR - M,
SCENAR-1-NT (version 02).

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous electrical nerve stimulator for pain relief

Regulatory Class: Class II

Product Code: GZJ

Dated: April 08, 2010

Received: April 23, 2010

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.

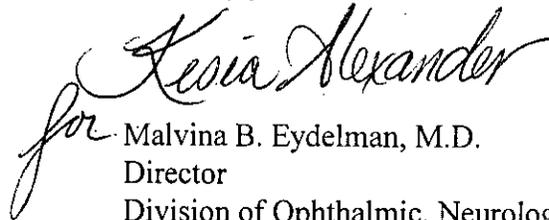
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 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,

A handwritten signature in cursive script that reads "Lesia Alexander". The signature is written in black ink and is positioned above the typed name and title.

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K092117

Device Name: CHANS-01-SCENAR,
CHANS-01-SCENAR - M,
SCENAR-1-NT (version 02).

Indications for Use:

For relief and management of chronic and acute pain, as adjunctive treatment in the management of post-surgical and post-traumatic pain.

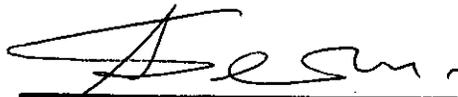
Prescription Use X
(21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use
(21 CFR Part 801 Subpart C)

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

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)



(Division Sign-Off)

Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K092117