K011880

APR 17 2002

# 510(K) SUBMISSION SUMMARY

Date of submission: June 11th 2001

*Submitter's References:*

**COMPEX SA**
Z.I. "Larges Pièces A"
Ch. du Dévent
CH – 1024 Écublens

Tel.: +41 (0)21 695 23 60
Fax: +41 (0)21 695 23 61
E-mail: info@compex.ch

*Official Correspondent:*

**Ansis M. Helmanis**
Barnes, Richardson & Colburn

Tel.: 202-457-0300
Fax: 202-331-8746
E-mail: ahelmanis@brc-dc.com

*Summary Contents:*

# 1. SUBMITTED DEVICE

| | |
|---|---|
| *Trade Name:* | ***"COMPEX® SPORT"*** |
| *Common Name:* | **Sport Muscle Stimulator** |
| *Classification Name:* | **Power Muscle Stimulator** |

## 1.1 Predicate/Legally Marketed Device

***"Compex® Sport"*** is a powered muscle stimulator substantially equivalent, in the perspective of technological characteristics, to ***"Compex® 2"*** (510(k) number: K940301).

## 1.2 Proposed Indications

The proposed indications for "Compex® Sport" differ from those of the predicate device because it has been created for a different intended use and for use without prescription.

**"Compex® Sport" is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.**

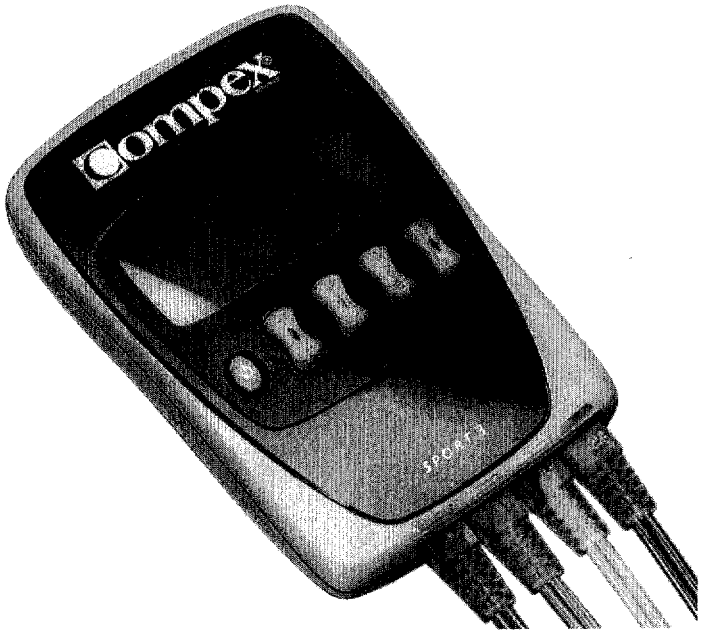
***"Compex® Sport"*** **is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the** ***"Compex® Sport"*** **training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.**

The *"Compex® Sport"* electrical impulses allow triggering action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that *"Compex® Sport"* can impose on the stimulated muscles are able to improve or facilitate muscle performance. ***"Compex® Sport"* may therefore be considered a technique of muscle training.**

# 2. DEVICE DESCRIPTION

**"Compex® Sport" is a portable, battery operated neuromuscular electrical stimulator.**
**Equipped with four channels, it works with a rechargeable battery and offers an easy-to-read LCD display.**




## 2.1 Physical Characteristics

Made out of a resistant plastic case ergonomically designed.

- *Length:* 142 mm
- *Width:* 99 mm
- Height: 36 mm
- Weight: 350g

*"Compex® Sport"* is equipped with one "on/off" button and four pairs of "+" and "–" keys, which control all the operating functions of the device and allow the adjustment of electrical intensity on each of the four channels.

## 2.2 Technical characteristics

- Four independent channels which electrical current can be regulated individually
- Biphasic rectangular impulses with electrical mean equal to zero
- Maximum output current per channel: 100 mA for a max. charge of 2200 Ohms
- Maximum quantity of electricity per channel: 40 µC
- Impulse width: 200 or 400 µS
- Range of pulse frequency: 1-120 Hz
- The electrical pulses generated by *"Compex® Sport"* are transmitted to the muscles via self-adhesive electrodes

## 2.3 Equipment

*"Compex® Sport"* is delivered in a suitcase containing the following items:

- *"Compex® Sport"* stimulator
- One battery charger
- One set of four electrode cables
- Four plastic bags containing self-adhesive electrodes (small and large)
- One User Manual
- One Booklet showing the various positions of the electrodes
- One CD-ROM (Training Planner) to help the user in choosing the adapted program and in preparing a personal training plan

# 3. STATEMENT OF INTENDED USE

The proposed indications for "Compex® Sport" differ from those of the predicate device because it has been created for a different intended use and for use without prescription.

**"Compex® Sport" is intended to stimulate healthy muscles in order to improve or facilitate muscle performance.**

***"Compex® Sport"* is not intended to be used in conjunction with therapy or treatment of medical diseases or medical conditions of any kind. None of the *"Compex® Sport"* training programs is designed for injured or ailing muscles and its use on such muscles is contraindicated.**

The *"Compex® Sport"* electrical impulses allow triggering action potentials on motoneurones of motor nerves (excitations). These excitations of motoneurones are transmitted to the muscle fibers via the motor endplate where they generate mechanical muscle fiber responses that correspond to muscle work. Depending on the parameters of the electrical impulses (pulse frequency, duration of contraction, duration of rest, total session duration), different types of muscle work can be imposed on the stimulated muscles.

The various types of muscle work that *"Compex® Sport"* can impose on the stimulated muscles are able to improve or facilitate muscle performance. ***"Compex® Sport"* may therefore be considered a technique of muscle training.**

## 3.1 Training Programs

*"Compex® Sport"* provides four muscle training programs:

### 3.1.1 "Endurance" Program

*"Compex® Sport"* Endurance program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to slow fibers during voluntary endurance exercises. It develops the aerobic metabolism of the stimulated fibers and their capillary supply. It improves resistance of the stimulated muscles to fatigue for long duration exercises of average medium working power level.

### 3.1.2 "Resistance" Program

*"Compex® Sport"* Resistance program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to fast fibers during voluntary heavy resistance exercises. It develops the glycolysis metabolism of the stimulated fibers and their capillary supply. It improves resistance of the stimulated muscles to fatigue for short duration exercises of average high working power level

### 3.1.3 "Strength" Program

*"Compex® Sport"* Strength program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to fast fibers during voluntary strength exercises. It develops the cross-sectional area of the stimulated fibers. It improves the maximum strength of isometric and dynamic contractions of the stimulated muscles.

### 3.1.4 "Explosive Strength" Program

*"Compex® Sport"* Explosive Strength program imposes on the stimulated muscle a pattern of activities resembling the one that is delivered by the nerve to fast fibers during voluntary rapid strength development exercises (ballistic movement). It develops the strength and/or the contraction speed of the stimulated fibers. It improves the explosive strength of the stimulated muscles.

## 3.2 Other Programs

*"Compex® Sport"* offers two other programs that are not intended to train muscles. Their objective is to prepare muscles for explosive motions or to facilitate recovery after active muscle training or competition.

### 3.2.1 "Potentiation" Program

*"Compex® Sport"* Potentiation program produces on the stimulated muscles the physiological muscle phenomenon known as "Twitch Potentiation". A muscle with potentiated fibers has more velocity and reaches its maximum strength more easily and rapidly.

### 3.2.2 "Active Recovery" Program

*"Compex® Sport"* Active Recovery program produces muscle twitches at a very low frequency. Those twitches act like a massage and induce an increase of the blood flow and a faster reduction of the lactic acid blood level. It facilitates recovery of the stimulated muscles after active muscle training or competition.

# 4. TECHNOLOGICAL EQUIVALENCE

## 4.1 Comparison between *"Compex® 2"* and *"Compex® Sport"*

| *"Compex® 2"* | *"Compex® Sport"* |
|---|---|
| Constant current generator | Same |
| Four independent channels with the possibility to regulate the current for each one individually | Same |
| Four channel isolated one from the other, and galvanically from the earth | Same |
| Multiplexing system of the four channels | Same |
| Electrode or channel fault safety system | Same |
| Biphasic rectangular impulses with electrical mean equal to zero | Same |
| Maximum output current per channel: 100 mA +/– 2 | Same |
| Maximum output current for a maximum skin charge of 2200 Ohms | Same |
| Maximum output voltage: 200 V +/– 10 | Same |
| Maximum rise time for 100 mA impulse: 2 µS | Same |
| ***Impulse width: 15 to 800 µS*** [1] | ***Impulse width: 200 and 400 µS*** [1] |
| ***Maximum quantity of electricity per channel: 80 µC*** [2] | ***Maximum quantity of electricity per channel: 40 µC*** [2] |
| ***Range of pulse frequency: 1 – 150 Hz*** [3] | ***Range of pulse frequency: 1 – 120 Hz*** [3] |

| *"Compex® 2"* | *"Compex® Sport"* |
|---|---|
| Power supply: NIMH rechargeable battery (7.2 V ≈ 1200 mA/h) | Same |
| Length: 148 mm<br>Width: 85 mm<br>Height: 30 mm | Length: 142 mm<br>Width: 99 mm<br>Height: 36 mm |
| ***Weight: 420 g*** | ***Weight: 350 g*** |
| ***Metallic case*** | ***Plastic case*** |
| Memory Eprom 2 Kbytes | Same |
| LCD type display | Same |
| – "on/off" switch<br>– 4 pairs of "+" and "–" buttons to control the operating functions | Same |
| Separate plug-in charger.<br>No possibility to activate the unit while the charger is connected | Same |
| Self-adhesive electrodes (Axelgaard type) | Same |

Note: (1) to (3) = Relevant differences; See comments on next page

## 4.2 Differences (Comments)

(1) The impulse width has to be adjusted to the chronaxia of the motor nerve that is excited. The chronaxia of the motor nerve of the muscles that can be stimulated with *"Compex® Sport"* ranges between 200 and 400 µS.

(2) The maximum quantity of electrical charge per channel depends on the maximum impulse width and the maximum current output. With a 100 mA maximum output and a 400 µS maximum impulse width, *"Compex® Sport"* produces a 40 µC maximum quantity of electrical charge.

(3) *"Compex® 2"* offers analgesic TENS programs that need frequencies going up to 150 Hz. Being only intended to stimulate muscles and not to generate analgesic effects, *"Compex® Sport"* doesn't need a maximum frequency going above 120 Hz. This value is indeed largely sufficient to get a maximum tetanization of the stimulated fibers.

# 5. SAFETY

## 5.1 Safety Data

*"Compex® Sport"* has been legally marketed without prescription in seven European countries (Switzerland, France, Italy, Belgium, Spain, Germany and the Netherlands) for more than four years. Marketing data and a post-marketing surveillance system have confirmed that *"Compex® Sport"* – with its specific safety measures and features – is safe and effective when used, without medical supervision, for the proposed indications to train muscles.

The first unit of sport stimulators (*"Compex® Sport"*) was sold in May 1996. Since then, Compex has sold more than 66'000 *"Compex® Sport"* devices in Europe.

No adverse events related to *"Compex® Sport"* have been reported to Compex. Twenty-six (26) consumer complaints have been received concerning the device. Compex investigated each of the consumer complaints and found that three (3) were related to reversible skin irritations, and twenty-three (23) to nothing more than to the fact that the consumer was "feeling something wrong" without resulting physical injury.

## 5.2 Specific Safety Features and Measures

In addition to the classical safety features for a power muscle stimulator, *"Compex® Sport"* also has specific safety measures and technical features.

### 5.2.1 Measures to Prevent Misuse

- Warning displayed on the LCD screen.
- To make the user conscious of the specific contraindicated conditions: warning in the User Manual.
- To avoid off-label uses: warning in the User Manual.
- To prevent misplacement of the electrodes: warning with pictures in the User Manual and on each plastic set of electrodes.

- To avoid the consequences of the placement of electrodes on skin lesions: warning with picture in the User Manual, picture on the plastic set of electrodes, technical current control of the stimulator to avoid current increasing output when skin resistance is low.

- To prevent the use of deteriorated or inappropriate electrodes: warning in the User Manual, technical impedance control with the so-called "Electrode default system".

- To prevent infections by electrodes that have been used by someone else: warning with picture in the User Manual, picture on the plastic set of electrodes.

### 5.2.2 Technical Safety Features

- Standard programs to avoid the risk that the user modifies the electrical parameters; the user can only adjust the electrical intensity.

- *"Compex® Sport"* LCD screen uses clear and straightforward pictograms that make its use quite easy.

- Any potential risk of electrochemical burns is avoided because the electrical impulses are biphasic rectangular impulses with electrical mean equal to zero.

- To avoid unexpected muscle response, all *"Compex® Sport"* programs always start with a nil electrical intensity, which the user can then increase as he wants.

- To prevent the power output of a channel to be added to the one of an other channel, *"Compex® Sport"* has been fitted out with four fully independent channels.

- To avoid the current density overstep the safety limit (10 $mA/mm^2$), which may cause electrical burns, *"Compex® Sport"* is equipped with a constant current generator.

- Prevention against skin burns and irritations is obtained by the combination of the constant current generator and the specific "Electrode default" mechanism.

# 6. EFFECTIVENESS

## 6.1 Effectiveness Data

*"Compex® Sport"* is a power muscle stimulator and, consequently, generates electrical impulses. Each of these impulses is intended to trigger an action potential (AP) on motor nerve fibers. In response to an AP, the muscle fibers carry out a mechanical elementary response, which is a mere unit of work. Depending on the way the electrical impulses are repeated, different types of working power are generated by muscle fibers. For example, a low impulse frequency of 10 Hz imposes a low working power on muscle fibers as with endurance training. On the other hand, a high frequency of 100 Hz imposes a high working power as with strength training.

### 6.1.1 Endurance

It is well demonstrated, in peer reviewed articles (see Section 8.2.1 of the 510k), and confirmed by physiologists that electrical stimulation provided to the muscles with a pattern of activity resembling the one that is delivered by the nerve to the slow muscles leads to an increasing resistance to muscle fatigue with aerobic metabolism and capillary blood supply development of muscle fibers.

### 6.1.2 Resistance

The fact that activity induces changes of skeletal muscle is a well-established physiologic fact. Provided that electrical stimulation imposes a regimen of activity on the muscles that brings about lactic acid production (i.e. that activates the glycolytic metabolism) and provided this regimen of activity is maintained long enough, the stimulated muscle will improve its resistance. Peer-reviewed articles (see Section 8.2.2 of the 510k) demonstrate that electrical stimulation with tetanic frequency, long contractions, and short rests is a resistance training exercise with activation of glycolysis and consequently morphological muscle fibers changes similar to those expected after voluntary heavy resistance exercises.

### 6.1.3 Strength

Peer-reviewed articles (see Section 8.2.3 of the 510k) demonstrate that electrical stimulation can increase isometric as well as dynamic muscle strength. Moreover, different studies have been carried out on sportsmen to examine whether electrical stimulation can bring about some strength performance improvement. Most of those studies were using Compex material.

### 6.1.4 Explosive Strength

Peer-reviewed articles (see Section 8.2.4 of the 510k) about a gain in strength with muscle stimulation by Compex demonstrated also an explosive muscle strength improvement.

### 6.1.5 Potentiation

Peer-reviewed articles confirm that potentiation on human skeletal muscle with electrical stimulation can be easily obtained (see Section 8.2.5 of the 510k).

### 6.1.6 Active Recovery

The so-called *"Compex® Sport"* "Active Recovery" program imposes a low level of activity to the stimulated muscles in order to facilitate their recovery. The electrical stimulation with low frequency acts as a massage. Moreover, electrical stimulation significantly increases muscle blood flow (one of the 6 classical claims for power muscle stimulators) and is demonstrated in a peer-reviewed article (see Section 8.2.6 of the 510k).

## 6.2 Specific Effectiveness Features and Measures

To ensure effectiveness, *"Compex® Sport"* has specific measures and technical features.

The appropriate way of using *"Compex® Sport"* is ensured by the *"Compex® Sport"* Training Planner on CD-ROM (choice of the appropriate program, choice of the muscle(s) to be stimulated, placement of the electrodes, number of sessions per week, cycle duration).

"Space recruitment" of muscular fibers is the fundamental and necessary feature of electrical muscle stimulation to ensure effectiveness. It corresponds to the number of muscle fibers that are stimulated or "recruited" by electrically induced stimulation. *"Compex® Sport"* ensures high space recruitment through a number of specific technical features (see Section 6.2 of the 510k).

# 7. CONCLUSIONS

*"Compex® Sport"* is substantially equivalent to the predicate device (*"Compex® 2"*) in terms of technical characteristics. *"Compex® Sport"* specifically differs from the predicate device with regards to the proposed indications for use and to the fact that he is to be used without medical prescription or supervision.

The safety of the device, to be uses for the proposed indications without medical prescription or supervisions is established by the fact that no adverse events has been reported during more than four years of actual marketing experience (with over 66'000 devices sold in 7 European countries). Among the 26 consumers' complaints that have been received, only 3 were related to physical concerns (minor skin irritations). This attests of the integrity of the physical and technical characteristics of the devices as well as of the ease of use and clarity of the detailed instructions for operation and warnings that are provided to the consumer either in the User Manual or in the CD-ROM that accompanies each device that is sold.

The effectiveness of the device for the proposed indications is supported by a number of articles in peer-reviewed publications, which demonstrate that electrical muscle stimulation does improve muscle endurance, resistance, strength, explosive strength, potentiation, and recovery. Moreover, the effectiveness of the device is further supported by a detailed muscle training program for each proposed indication that takes the consumer step-by-step through the program.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 17 2002

Ansis M. Helmanis
Representing Compex, S.A.
Barnes, Richardson & Colburn
1225 Eye Street, N.W., Suite 1150
Washington, D.C. 20005

Re: K011880
Trade/Device Name: Compex® Sport, Model Sport 3
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered Muscle Stimulator
Regulatory Class: Class II
Product Code: NGX
Dated: January 17, 2002
Received: January 17, 2002

Dear Mr. Helmanis:

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) 594-4659. 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). 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 Mark N. Melkerson

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

510(k) NUMBER (IF KNOWN) : K011880

DEVICE NAME : Compex Sport

INDICATIONS FOR USE:

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

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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)

for Mark N Melkerson

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

510(k) Number K011880