December 14, 2021

TimeWaver Production GmbH
% Douglas Herrington
Principal Consultant
Herrington Consulting LLC
2885 Sanford Ave SW 43083
Grandville, Michigan 49418

Re: K212832
Trade/Device Name: TimeWaver Frequency
Regulation Number: 21 CFR 890.5850
Regulation Name: Powered muscle stimulator
Regulatory Class: Class II
Product Code: IPF, GZJ
Dated: August 2, 2021
Received: September 7, 2021

Dear Douglas Herrington:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

CDR Jitendra Virani, MS
Assistant Director
DHT5B: Division of Neuromodulation
and Physical Medicine Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
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: 06/30/2023
*See PRA Statement below.*

510(k) Number *(if known)*
K212832

Device Name
TimeWaver Frequency

Indications for Use *(Describe)*
As an NMES device, indications are for the following conditions:
-Relaxation of muscle spasms
-Retardation or prevention of disuse atrophy
-Increased local blood circulation
-Re-Educating muscles
-Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis
-Maintaining or increasing range of motion.

As a TENS device, indications are for the following conditions:
-Symptomatic relief and management of chronic intractable pain
-Adjunctive treatment for post-surgical and post-traumatic acute 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)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

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# 510(k) Summary: K212832

[As required by 21 CFR 807.92]

**General Information**

**Date:** December 13, 2021

Type of 510(k) Submission: Traditional 510(k) Notification

Sponsor & Manufacturing Address:

TimeWaver Production GmbH
Schloss Kränzlin, Darritzer Straße 6
16818 Kränzlin, Germany
Phone: +49 3391 40022-11
FAX: +49 3391 40022-99
Registration Number: 3009411292

Official Contact Name

Douglas Herrington
Principal Consultant
Herrington Consulting LLC
2885 Sanford Ave, SW#43083
Grandville, MI 49418-1342
Telephone: 1.248.369.5564
Fax: 1.877.881.4412
E-mail: dgls_herrington@yahoo.com

**Regulatory Information**

Device Name: TimeWaver Frequency
Model Number: REF 0002

Panel Code: 89 Physical Medicine
Classification: Class II
Product Code(s) and Regulation Numbers:

| Product Code | Regulations Number | Regulation Name | |
|---|---|---|---|
| IPF | 890.5850 | Powered Muscle Stimulator | Primary Code |
| GZJ | 882.5890 | Transcutaneous electrical nerve stimulator | Secondary Code |

**Predicate Device**
510k Number: K150413,
Manufacturer: CyMedica Orthopedics
Model: QB1 Powered Muscle Stimulator System (NMES) & Transcutaneous Electrical Nerve Stimulator (TENS) QB-1000
Classification: Class II

**DEVICE DESCRIPTION [807.92(a)(4)]**

TimeWaver Frequency is an electrical stimulation device that supports the treatment of symptoms of specific medical conditions, using currents in the microampere range with different frequencies. It can be applied to different areas of the body and is a multifunctional electrotherapy device with two stimulation channels and two treatment modes that deliver neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulations (TENS).

The TimeWaver Frequency device is a prescription device intended to be used by healthcare providers in a healthcare setting and is not approved for use in a home environment. The use of the device on a particular patient is solely the decision of the medical professional, who is responsible for having the proper training and exercising his or her informed medical judgement.

The principals of electrotherapy correspond to the process observed during voluntary muscle contraction. NMES pulses stimulate motor points of target muscles, causing muscle contraction. This can help re-educate and strengthen muscles following injury or surgery. TENS blocks the pain signal sent from the affected area on nerve pathways.

The TimeWaver Frequency device provides 6 treatment programs for NEMS and two treatment programs for TENS. The NMES programs are for relaxation of muscle spasms, disuse atrophy, blood circulations, re-educating muscles, stimulation of calf muscles, and range of motion. The TENS programs are for chronic pain and acute pain. In all modes adhesive electrodes are used to deliver the stimulation.

The TimeWaver Frequency is controlled by an application software program. A personal computer or a notebook is necessary to install the application software and is not provided with the TimeWaver Frequency system. The TimeWaver Frequency software must be used as a stand-alone application on its own computer, which is not used for other software applications. The user interface has several sections. The title bar contains the current program version, the lower status bar shows if hardware components are correctly connected, and the menu bar allows selection of the section to work within. The software requires setting up a new client to include relevant patient information. Treatments are conducted by selecting the appropriate treatment from the Programs module.

The TimeWaver Frequency device operates using an external power supply and/or an internal battery. It is supplied with instructions for use, the TimeWaver Frequency device, power supply, USB cable, electrode connector cables, 50mm x 50mm and 50mm x 90 mm adhesive electrodes.

**Indication for Use Statement**

As an NMES device, indications are for the following conditions:

1. -Relaxation of muscle spasms
2. -Retardation or prevention of disuse atrophy
3. -Increased local blood circulation
4. -Re-Educating muscles
5. -Immediate post-surgical stimulation of leg and arm muscles
6. -Maintaining or increasing range of motion.

| Treatment Program | Pulse Shape | Duration | Frequency | Pulse Width | Duty Cycle | Work Cycle | Relaxation Time | Contraction Time | Rest Time | Indication Numbers |
|---|---|---|---|---|---|---|---|---|---|---|
| NMES Post-Op | Monophasic | 20 min | 50 pps | 5 ms | 25 % | 13 s | 10 s | 3 s | 3.4 s | 1, 2, 3, 4, 5, 6 |
| | | | | | | | | 2 cycles | | |
| NMES Strength | Monophasic | 20 min | 50 pps | 5 ms | 25 % | 13 s | 10 s | 1 s | 1.4 s | 1, 2, 3, 4, 5, 6 |
| | | | | | | | | 5 cycles | | |

As a TENS device, indications are for the following conditions:

7. Symptomatic relief and management of chronic intractable pain
8. Adjunctive treatment for post-surgical and post-traumatic acute pain

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| TENS Pain Management | Biphasic, symmetrical | 20 min | 100 pps | 1 ms | 20% | Continuous | 4 ms | 7 & 8 |

**Comparison of Technological Characteristics with the Predicate Device**

Considering technological characteristics, the TimeWaver Frequency device is similar to the predicate with only minor differences.

The TimeWaver Frequency and CyMedica QB-1 devices are both electrotherapy devices with the two treatment modes of neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS). They are both prescription devices intended for use under the direction of a medical provider and have the same indications for use. In addition, both products have the same product codes IPF (CFR 890.5850) and GZJ (CFR 882.5890).

In general, the TimeWaver Frequency output parameters are substantially the same as the output parameters for CyMedica QB-1. For example, the maximum current density (mA/cm2) for TimeWaver Frequency @ 500 ohms is 0.16, while the CyMedica QB-1 is 0.27. The maximum average power density (mW/cm2) @500 ohms is 2.0 for TimeWaver Frequency, whereas the CyMedica QB-1 maximum average power density @500 ohms is 1.0. The TimeWaver Frequency and CyMedica QB-1 both use pulsed monophasic and symmetric biphasic to deliver treatment programs.

TimeWaver has completed comprehensive design verification testing, electrical safety and electromagnetic compatibility testing, software verification and validation to ensure that the TimeWaver Frequency device performs as intended. The patient-contacting material has been verified to demonstrate acceptable biocompatibility. The electrodes and cables comply with 21 CFR 898, so they do not raise new questions of safety or effectiveness.

The minor differences in labeling and technological characteristics between the proposed device and the predicate device have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed TimeWaver Frequency is substantially equivalent to the predicate device.

The following table summarizes the specifications and features of the proposed TimeWaver Frequency device and the predicate device.

**Substantial Equivalence Summary**

| **Basic Unit Characteristics** | | | |
|---|---|---|---|
| **510(k) Number** | **Current Submission** | **K150413** | **Comparison** |
| Device Name/Model | TimeWaver Frequency, REF 0002 | QB1 & QB-1000, (NEMS) & (TENS) | N/A |
| Indications for Use | As an NMES device, indications are for the following conditions:<br>-Relaxation of muscle spasms<br>-Retardation or prevention of disuse atrophy<br>-Increased local blood circulation<br>-Re-Educating muscles<br>-Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis<br>-Maintaining or increasing range of motion.<br><br>As a TENS device, indications are for the following conditions:<br>-Symptomatic relief and management of chronic intractable pain<br>-Adjunctive treatment for post-surgical and post-traumatic acute pain | The QB1 Powered Muscle Stimulator System (NMES) &Transcutaneous Electrical Nerve Stimulator System (TENS); QB-1000 is a multifunctional electrotherapy device with two treatment modes that allow for neuromuscular electrical stimulation (NMES) and transcutaneous electrical nerve stimulation (TENS).<br><br>Indications for Use:<br>As an NMES device, indications are for the following conditions:<br>- Relaxation of muscle spasms<br>- Retardation or prevention of disuse atrophy<br>- Increasing local blood circulation<br>- Re-educating muscles | Same |

| | | | |
|---|---|---|---|
| | | - Immediate post-surgical stimulation of calf muscles to prevent venous thrombosis<br>- Maintaining or increasing range of motion<br><br>As a TENS device, indications are for the following conditions:<br>- Symptomatic relief and management of chronic intractable pain<br>- Adjunctive treatment for post-surgical and post-trauma acute pain | |
| Manufacturer | TimeWaver Production GmbH | CyMedica Orthopedics Inc | N/A |
| Power Source: | Power Supply Adapter/Battery | Battery | Different, but does not raise different questions of safety and effectiveness |
| - Battery | | | |
| - Number | 1 | 1 | |
| - Size | 3200 mAh, 3.7 V | 3.7V | |
| - Type | Lithium Polymer | Lithium Ion | |
| - Power Supply Adapter | | | Different, but does not raise different questions of safety and effectiveness |
| - Input | 100 - 240 V AC, 50 - 60 Hz, 0.5 A | N/A | |
| - Output | 9 V DC, 2.0 A | N/A | |
| - Method of Line Current Isolation | Power Supply Adapter | N/A | Different, but does not raise different questions of safety and effectiveness |
| - Patient Leakage Current (uA) | | | Same |
| - normal Condition, uA | <100µA | Pass | |

| | | | |
|---|---|---|---|
| - Single Fault Condition, uA | <100µA | Pass | |
| Number of Output Modes | 2 | 2 | Same |
| Number of Output Channels | 2 | 2 | Same |
| - Synchronous or Alternating | Alternating | Unknown | Different, but does not raise different questions of safety and effectiveness |
| - Method of Channel Isolation | galvanic isolation | Unknown | Different, but does not raise different questions of safety and effectiveness |
| Regulated Current or Regulated Voltage | both | both | Same |
| Software/Firmware/Microprocessor Control? | yes | yes | Same |
| Automatic Overload Trip | yes | yes | Same |
| Automatic No Load Trip | yes | yes | Same |
| Automatic Shut Off | Yes, PC-software | Yes, PC-software | Same |
| User Override Control | Yes, PC-software | Unknown | Different, but does not raise different questions of safety and effectiveness |
| Indicator Display | | | |
| On/Off Status? | yes | yes | Same |
| Low Battery? | yes | yes | Same |
| Voltage/Current Level? | yes | Unknown | Different, but does not raise different questions of safety and effectiveness |

| | | | |
|---|---|---|---|
| Compliance with Voluntary standards | IEC 60601-1<br>IEC 60601-1-2<br>IEC 60601-1-6<br>IEC 60601-2-10<br>ISO 10993-1: 2009<br>ISO 10993-5 | IEC 60601-1<br>IEC 60606-1-2<br>IEC 60601-2-10<br>IEC 60601-1-6<br>IEC 60601-1-11<br>IEC 62366: 2007<br>ISO 10993-1: 2009<br>ISO 10993-5: 2009<br>ISO 10993-10: 2010<br>ISO 14971: 2007 | Different, but does not raise different questions of safety and effectiveness |

**Output Specification**

| **510(k) Number** | **Current Submission** | | | | **K150413** | | | **Comparison** |
|---|---|---|---|---|---|---|---|---|
| Product Code (s) | IPF, GZJ | | | | IPF (NMES), GZJ (TENS) | | | N/A |
| Device Name | TimeWaver Frequency | | | | QB1 & QB1000 | | | N/A |
| Manufacturer | TimeWaver Production GmbH | | | | CyMedica Orthopedics Inc | | | N/A |
| Program Modes/Name | pulsed monophasic | symmetric biphasic | pulsed monophasic | symmetric biphasic | NEMS Post-Op | NEMS Strength | TENS | N/A |
| Output Mode (voltage or Current) | Current | Current | Voltage | Voltage | Both | Both | Both | Different, but does not raise different questions of safety and effectiveness |
| Waveform | Pulsed Monophasic | Symmetric Biphasic | Pulsed Monophasic | Symmetric Biphasic | Pulsed Monophasic | Pulsed Monophasic | Symmetric Biphasic | Same |
| Shape | rectangle | rectangle | rectangle | rectangle | Complex | Complex | Complex | Different, but does not raise |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | different questions of safety and effectiveness |
| Max Output Voltage (V) +/- 20% | | | | | | | | |
| 500 Ohms | 0.25 | 0.10 | 5.0 | 2.0 | 3.4 | 3.4 | 0.180 | Different, but does not raise different questions of safety and effectiveness |
| 2k Ohms | 1.2 | 0.4 | 5.0 | 2.0 | 6.1 | 6.1 | 0.190 | |
| 10k Ohms | 12.0 | 2.0 | 5.0 | 2.0 | 8.5 | 8.5 | 0.200 | |
| Max Output Current (mA) +/- 20% | | | | | | | | |
| 500 Ohms | 0.5 | 0.2 | 10.0 | 4.0 | 6.8 | 6.8 | 0.36 | Different, but does not raise different questions of safety and effectiveness |
| 2k Ohms | 0.5 | 0.2 | 2.5 | 1.0 | 3.0 | 3.0 | 0.10 | |
| 10k Ohms | 0.5 | 0.2 | 0.5 | 0.2 | 0.9 | 0.9 | 0.02 | |
| Frequency, Hz | 50 | 100 | 50 | 100 | 50 | 50 | 100 | Same |
| Duration of primary (depolarizing) phase (u sec) | 5000 | 1000 | 5000 | 1000 | 5000 | 5000 | N/A (continuous) | Different, but does not raise different questions of safety and |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | effectiveness |
| Pulse Duration, uSec | 5000 | 1000 | 5000 | 1000 | 5000 | 5000 | 1000 | Same |
| Net Charge uC per pulse | 2.5 | 0 (symmetric Biphasic) | 50 | 0 (symmetric Biphasic) | 126 | 126 | 0 (symmetric Biphasic) | Different, but does not raise different questions of safety and effectiveness |
| Maximum Phase Charge (uC), 500 Ohms | 2.5 | 0.2 | 50 | 4 | 126 | 126 | 43 | Different, but does not raise different questions of safety and effectiveness |
| Maximum Current Density, $mA/cm^2$ @ 500 Ohms | 0.020 | 0.008 | 0.400 | 0.160 | 0.270 | 0.270 | 0.014 | Different, but does not raise different questions of safety and effectiveness |
| Maximum Average Power Density [$mW/cm^2$] @ 500 Ohms | 0.005 | 0.001 | 2.000 | 0.320 | 1.000 | 1.000 | 0.0026 | Different, but does not raise different questions |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| | | | | | | | | of safety and effectiveness |

| | | | |
|---|---|---|---|
| Electrode Sizes | 50 x 50 mm, 25 $cm^2$<br>50 x 90 mm, 45 $cm_2$ | 25.86 $cm^2$<br>51.61 $cm^2$<br>51.61 $cm^2$ | Different, but does not raise different questions of safety and effectiveness |

# 510(k) Summary: K212832

[As required by 21 CFR 807.92]

**PREDICATE DEVICE(S) [807.92(a)(3)]**

The TimeWaver Frequency device is substantially equivalent to the predicate device, the CyMedica Orthopedics QB1 powered Muscle Stimulator (NEMS) & Transcutaneous Electrical Nerve Stimulator (TENS) with regard to product labeling, intended use, performance testing, technological and safety characteristics.

**COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES, [807.92(a)(6)]**

Regarding technological characteristics, the TimeWaver Frequency device is similar to the predicate's functions with only minor technological differences.

The CyMedical QB-1 product is targeted at knee rehabilitation, while the TimeWaver Frequency is more traditional in its approach to NMES and TENS treatment leaving specific treatment options to the judgement of a medical professional. While the treatment areas are different the output parameters of both devices are quite similar.

The CyMedica device provides 3 electrodes, where the TimeWaver Frequency provides 2 electrodes, which is more common in NEMS and TENS devices, and allows the device to be used in multiple locations. The combined surface area of the CyMedica electrodes is 129 $cm^2$ and the TimeWaver Frequency is 90 $cm^2$. This does not pose new questions of safety or efficacy as the maximum power density and maximum current density is similar to the CyMedica device.

The CyMedica device is used in conjunction with a conductive garment to facilitate electrode placement for knee treatment. As a traditional NEMS/TENS device TimeWaver Frequency does not limit treatment application to the knee area. TimeWaver Frequency use is limited to health care professionals, where CyMedica allows home use, so limiting electrode placement to what is allowable with the garment is not required. This does not pose new questions of safety or efficacy.

The CyMedica device has only limited treatment options available to the user that are activated by simple on product buttons for Post Op or Strength and intensity level adjustment for knee or thigh treatment. The TimeWaver Frequency uses software installed on a PC to control the treatment applications at the direction of the medical professional. As the maximum outputs of the TimeWaver Frequency device are controlled by the software, this does not pose any new questions of safety or efficacy.

TimeWaver has completed comprehensive design verification testing, electrical safety and electromagnetic compatibility testing, software verification and validation to ensure that the TimeWaver Frequency device performs as intended. The TimeWaver Frequency also passed all testing requirements for electrical safety and EMC, and the device adhesive electrode has been previously cleared by FDA. The minor differences in labeling and technological characteristics between the proposed device and the predicate device have been evaluated and determined to not raise different questions of safety or effectiveness. As such, the proposed TimeWaver Frequency is substantially equivalent to the predicate device.

**Performance Data [807.92(b)]**

All necessary non-clinical testing was conducted on the TimeWaver Frequency device to confirm that the device performs as intended.

**Nonclinical Testing Summary:**

The nonclinical, bench testing included performance verification to confirm acceptable performance of device features and functions. Other nonclinical safety testing included:

- Electrical safety and electromagnetic compatibility testing
- Biocompatibility verification
- Software verification and validation

The collective results of the nonclinical testing demonstrate that the materials chosen, the manufacturing processes, and design of the TimeWaver Frequency meet the established specifications.

**Performance Data: Electromagnetic Compatibility and Electrical Safety**
The TimeWaver Frequency device has been thoroughly tested against applicable EN and IEC standards by a third party and found to be compliant with the applicable sections. It was functionally tested and found to be compliant with the specification. The applicable electrical and safety standards met are:

IEC 60601-1: Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
IEC 60601-1-2: Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-1-6 Medical electrical equipment Part 1-6 General requirements for safety - Collateral Standard: Usability
IEC 60601-2-10: Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
ANSI/AAMI NS4:2013/ (R)2017: Transcutaneous electrical nerve stimulators

**Software Validation**
The TimeWaver Frequency device software was validated following FDA's Guidance for the Content of Premarket Submissions for Software contained in Medical Devices.

The applicable software validation standards met are:
EN ISO 13485: 2012_ Medical devices – Quality management systems – Requirements for regulatory purposes
EN ISO 14971: 2012_ Medical devices – Application of risk management to medical devices
EN 62304: 2006_ Medical device software – Software life cycle processes

**Biocompatibility Data**
Biocompatibility testing is not required because the primary patient contact surface is through the adhesive electrode which was previously cleared by FDA under K091163.

**Conclusion**
Based upon the intended use and technical information provided in this pre-market notification, the TimeWaver Frequency device has been shown to be substantially equivalent to the currently marketed predicate device.