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

November 13, 2015

BTL Industries, Inc.
Attn: Mr. Jan Zarsky
Executive Vice President
47 Loring Drive
Framingham, MA 01702

Re: K150353
Trade Name: BTL-4000
Regulation Number: 21 CFR 890.5860
Regulation Name: Ultrasound and muscle stimulator
Regulatory Class: Class II
Product Code: IMG, IPF, GZJ, GZI, LIH, ILY
Dated: October 12, 2015
Received: October 14, 2015

Dear Mr. Zarsky:

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 27f 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 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. 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,

Carlos L. Pena -S

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)*
K150353

Device Name
BTL-4000

Indications for Use *(Describe)*
ELECTROTHERAPY

VMS, VMS Burst, Russian, Monophasic Hi-Volt (NMES). Interferential and Premodulated (IFS) are indicated for relaxation of muscle spasms; prevention or retardation of disuse atrophy; increase of local blood circulation; muscle reeducation; maintaining or increasing range of motion and immediate postsurgical stimulation of calf muscles to prevent venous thrombosis.

Microcurrent, Interferential, Premodulated (IFS), VMS, VMS Burst, Asymmetrical Biphasic (TENS) and Symmetrical Biphasic (TENS) are indicated for symptomatic relief and management of chronic, intractable pain; post-traumatic acute pain and post-surgical acute pain.

FES is indicated for stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient's gait.

DC Continuous Mode is indicated for relaxation of muscle spasm.

ULTRASOUND THERAPY
Ultrasound module is indicated for an application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as: relief of pain, muscle spasms and joint contractures; relief of pain, muscle spasms and joint contractures that may be associated with: adhesive capsulitis, bursitis with slight calcification, myositis, soft tissue injuries, shortened tendons due to past injuries and scar tissues; relief of sub-chronic, chronic pain and joint contractures resulting from: capsular tightness, capsular scaring.

LASER THERAPY
Laser module is indicated for topical heating for: temporary increase of local blood circulation; temporary relief of minor muscle and joint aches, pains, and stiffness; relaxation of muscles; temporary relief of muscle spasms and temporary relief of minor pain and stiffness associated with arthritis.

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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# Section 5 – 510(k) Summary

## General Information

Sponsor:
BTL Industries, Inc.
47 Loring Drive
Framingham, MA 01702
Tel: +1-866-285-1656
Fax: +1-888-499-2502

Applicant:
BTL Industries, Inc.
47 Loring Drive
Framingham, MA 01702
Tel: +1-866-285-1656
Fax: +1-888-499-2502

Contact Person:
Jan Zarsky
BTL Industries, Inc.
Executive VP
zarsky@btlnet.com

Summary Preparation Date:
5 February, 2015

## Device Names

Trade/Proprietary Name:
BTL-4000

Classification Name:

21 CFR 890.5300 Ultrasonic diathermy
21 CFR 890.5500 Infrared lamp
21 CFR 890.5850 Powered muscle stimulator
21 CFR 890.5860 Ultrasound and Muscle stimulator
21 CFR 882.5890 TENS for pain relief
21 CFR 882.5810 External functional neuromuscular stimulator

Product Code:

GZI – Stimulator, Neuromuscular, External Functional
GZJ – Stimulator, Nerve, Transcutaneous, for Pain Relief
ILY – Lamp, Infrared, Therapeutic Heating
IMG – Stimulator, Ultrasound and Muscle, for Use in Applying Therapeutic Deep Heat
IPF – Stimulator, Muscle, Powered
LIH – Interferential Current Therapy

## Legally Marketed Predicate Devices

BTL-4000 is substantially equivalent to the current products that are already cleared for USA distribution under the following 510(k) Premarket Notification numbers:

- Vectra Genisys – Chattanooga Medical Supply, Inc. (K031077)
- Vectra Genisys Laser Module – Chattanooga Medical Supply, Inc. (K040662)

## Product Description

BTL-4000 is a professional physiotherapy device. Depending on the required configuration, the device can consist of up to three generators – electrotherapy, ultrasound therapy and laser therapy.

Electrotherapy is a non-invasive therapeutic method based on electrical current flow through the human tissues. The electric current is applied with the use of electrodes directly through the patient's skin. The use of electrotherapy is accepted in the field of rehabilitation. Ultrasound therapy is a non-invasive therapeutic method, which uses mechanical energy of the longitudinal waves penetrating deep through human soft-tissues. Mechanical waves are absorbed in the tissues and transformed into heat energy.Low-level laser therapy is a non-invasive therapeutic method based on the application of coherent, polarized, monochromatic light in the form of a laser beam. The laser beam is absorbed in the tissues.

BTL-4000 is equipped with a colour touch screen, which considerably simplifies its operation. Therapy is simply started by a quick selection from the list of the most frequently used therapeutic protocols or by selecting from the list of all therapeutic protocols. A sophisticated function of the device is the possibility to select the optimum therapy according to the required therapeutic effect or according to the place of application.

The BTL-4000 consists of the following main components:

- control unit
- user interface with 7“ LCD color touch screen
- therapy modules - electrotherapy, ultrasound and laser
- accessories depends on the combination - electrotherapy electrodes
  - laser probe/cluster
  - ultrasound head/HandsFree sono handpiece

# Indications for Use

## For Electrotherapy

For VMS, VMS Burst, Russian, Monophasic Hi-Volt (NMES), Interferential and Premodulated (IFS):

- relaxation of muscle spasms
- prevention or retardation of disuse atrophy
- increase of local blood circulation
- muscle re-education
- maintaining or increasing range of motion
- immediate postsurgical stimulation of calf muscles to prevent venous thrombosis

Additionally for Microcurrent, Interferential, Premodulated (IFS), VMS, VMS Burst, Asymmetrical Biphasic (TENS) and Symmetrical Biphasic (TENS):

- symptomatic relief and management of chronic, intractable pain
- post-traumatic acute pain
- post-surgical acute pain

For FES:

Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient´s gait.

For DC Continunous Mode:

- relaxation of muscle spasm

## For Ultrasound:

Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:

- relief of pain, muscle spasms and joint contractures
- relief of pain, muscle spasms and joint contractures that may be associated with:
  - adhesive capsulitis
  - bursitis with slight calcification
  - myositis
  - soft tissue injuries
  - shortened tendons due to past injuries and scar tissues
- relief of sub-chronic, chronic pain and joint contractures resulting from:
  - capsular tightness
  - capsular scarring

**For Laser:**
Is indicated for topical heating for:

- temporary increase of local blood circulation
- temporary relief of minor muscle and joint aches, pains, and stiffness
- relaxation of muscles
- temporary relief of muscle spasms
- temporary relief of minor pain and stiffness associated with arthritis

## Non-clinical Testing

The BTL-4000 device has been thoroughly evaluated for electrical safety. The BTL-4000 has been found to conform with applicable medical device safety standards. The system complies with the following standards:

ISO 14971 – Medical devices – Application of risk management to medical devices
IEC 62304 – Medical Device Software – Software Life Cycle Processes

Medical Electrical Equipment

| | |
|---|---|
| IEC 60601-1 | General requirements for safety |
| IEC 60601-1-2 | Electromagnetic compatibility–Requirements and Tests |
| IEC 60601-2-5 | Particular requirements for the basic safety and essential performance of ultrasonic physiotherapy equipment |
| IEC 60601-2-10 | Particular requirements for the basic safety and essential performance of nerve and muscle stimulators |
| IEC 60601-2-22 | Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment |
| IEC 60825-1 | Safety of laser products - Part 1: Equipment classification and requirements |
| IEC 60601-1-6 | General requirements for basic safety and essential performance - Collateral standard: Usability |
| ISO 10993-1 | Evaluation and testing within a risk management process |
| ISO 10993-5 | Biological Evaluation of Medical Devices–Tests for In Vitro toxicity |
| ISO 10993-10 | Biological Evaluation of Medical Devices–Test for Irritation and Skin Sensitization |

ISO 14971 – Medical devices – Application of risk management to medical devices
IEC 62304 – Medical Device Software – Software Life Cycle Processes

## Clinical testing

The substantial equivalence determination for the BTL-4000 is not based upon clinical performance testing. The device safety and efficacy was demonstrated by comparison of technical characteristics between the BTL-4000 and compared to the predicate device.

# Comparison with the Predicate Device

| Device Name | BTL-4000 | Vectra Genisys | Vectra Genisys Laser System |
|---|---|---|---|
| **Manufacturer** | BTL Industries, Inc. | Chattanooga Medical Supply, Inc. | Chattanooga Medical Supply, Inc. |
| **510(k) Number** | Current submission | K031077 | K040662 |
| **Intended Use** | For VMS, VMS Burst, Russian, Monophasic Hi-Volt (NMES), Interferential and Premodulated (IFS):<br>- relaxation of muscle spasms<br>- prevention or retardation of disuse atrophy<br>- increase of local blood circulation<br>- muscle re-education<br>- maintaining or increasing range of motion<br>- immediate postsurgical stimulation of calf muscles to prevent venous thrombosis<br><br>Additionally for Microcurrent, Interferential, Premodulated (IFS), VMS, VMS Burst, Asymmetrical Biphasic (TENS) and Symmetrical Biphasic (TENS):<br>- symptomatic relief and management of chronic, intractable pain<br>- post-traumatic acute pain<br>- post-surgical acute pain<br><br>For FES:<br>Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient´s gait.<br><br>For DC Continuous Mode:<br>- Relaxation of muscle spasm<br><br>For Laser:<br>the laser module is indicated for topical heating for:<br>-temporary increase in local blood circulation<br>-temporary relief of minor muscle and joint aches, pains, and stiffness<br>-relaxation of muscles<br>-temporary relief of muscle spasms<br>-temporary relief of minor pain and stiffness associated with arthritis<br><br>For Ultrasound<br>Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:<br>- relief of pain, muscle spasms and joint contractures<br>- relief of pain, muscle spasms and joint contractures that may be associated with:<br>-adhesive capsulitis<br>-bursitis with slight calcification<br>-myositis<br>-soft tissue injuries<br>-shortened tendons due to past injuries and scar tissues<br>-relief of sub-chronic, chronic pain and joint contractures resulting from:<br>-capsular tightness<br>-capsular scarring | For VMS, VMS Burst, Russian, Monophasic Hi-Volt (NMES), Interferential and Premodulated (IFS):<br>- relaxation of muscle spasms<br>- prevention or retardation of disuse atrophy<br>- increase of local blood circulation<br>- muscle re-education<br>-maintaining or increasing range of motion<br>- immediate postsurgical stimulation of calf muscles to prevent venous thrombosis<br><br>Additionally for Microcurrent, Interferential, Premodulated (IFS), VMS, VMS Burst, Asymmetrical Biphasic (TENS) and Symmetrical Biphasic (TENS):<br>- symptomatic relief and management of chronic, intractable pain<br>- post-traumatic acute pain<br>- post-surgical acute pain<br><br>For FES:<br>Stimulation of the muscles in the leg and ankle of partially paralyzed patients to provide flexion of the foot and thus improve the patient´s gait.<br><br>For DC Continuous Mode:<br>- Relaxation of muscle spasm<br><br>For EMG:<br>To determination the activation timing of muscles for a) retraining of muscle activation b) coordination of muscle activation An indication of the force produced by muscle for control and maintenance of muscle contractions. Relaxation muscle training. Muscle re-education<br><br>For EMG triggered Stim:<br>Stroke rehab by muscle re-education<br>Relaxation of muscle spasm<br>Prevention of retardation of disuse atrophy<br>Increase local blood circulation<br>Muscle re-education<br>Maintaining or increase range of motion<br><br>For Ultrasound:<br>Application of therapeutic deep heat for the treatment of selected sub-chronic and chronic medical conditions such as:<br>-relief of pain, muscle spasms and joint contractures<br>-relief of pain, muscle spasms and joint contractures that may be associated with:<br>-adhesive capsulitis<br>-bursitis with slight calcification<br>-myositis<br>-soft tissue injuries<br>-shortened tendons due to past injuries and scar tissues<br>-relief of sub-chronic, chronic pain and joint contractures resulting from:<br>-capsular tightness<br>-capsular scarring | Vectra Genisys (Intelect XT) Laser Module and Vectra Genisys (Intele XT) Laser Transportable Systems are indicated for topical heating for:<br><br>-temporary increase in local blood circulation<br>-temporary relief of minor muscle and joint aches, pains, and stiffness<br>-relaxation of muscles<br>-temporary relief of muscle spasms<br>-temporary relief of minor pain and stiffness associated with arthritis |

| Device Name | BTL-4000 | Vectra Genisys | Vectra Genisys Laser System |
|---|---|---|---|
| **Manufacturer** | BTL Industries, Inc. | Chattanooga Medical Supply, Inc. | Chattanooga Medical Supply, Inc. |
| **510(k) Number** | Current submission | K031077 | K040662 |
| **Product Code** | GZI<br>GZJ<br>ILY<br>IMG<br>IPF<br>LIH | GZI<br>GZJ<br>IMG<br>IPF<br>HCC<br>LIH | ILY |
| **Electrical Protection** | Class II, BF | Class I, BF | Class I, B |
| **Dimensions** | 380×190×260 mm | 289×222×324 mm | 288mm(with applicator) / 239mm(without applicator)×163mm×328mm |
| **Power Voltage and Frequency** | ~ 100 V to 240 V AC, 50-60 Hz | ~ 100 V to 240 V AC, 50-60 Hz | ~ 100 V to 240 V AC, 50-60 Hz |
| **Covering Grade** | IP20 | IPX0 | unknown |
| **Display** | colour, touchscreen | colour, display | |
| **Trolley available** | yes | yes | yes |
| **Body areas Indication** | yes | yes | yes |
| **Battery module** | optional | optional | yes |
| **Operating Conditions** | 10 °C to +30 °C<br>30 % to 75 %<br>700 hPa to 1,060 hPa | 100–240 V - 1.0 A, 50/60 Hz | 10 °C to +30 °C<br>30 % to 75 %<br>700 hPa to 1,060 hPa |
| **Electrotherapy Module** | | | |
| **Electrical protection** | BF | BF | N/A |
| **Number of channels** | 2; 4 | 2; 4 | N/A |
| **Output Intensity** | 0–500 V, 0–200 mA | 0–500 V, 0–200 mA | N/A |
| **Electrotherapy Currents** | IFC – Interferential (Traditional 4 Pole)<br>Premodulated (Traditional 2 Pole IFC)<br>TENS – Symmetrical Biphasic<br>TENS – Asymmetrical Biphasic<br>Russian<br>Direct Current<br>Microcurrent<br>High Voltage Pulsed Current (HVPC)<br>VMS, VMS Burst | IFC – Interferential (Traditional 4 Pole)<br>Premodulated (Traditional 2 Pole IFC)<br>TENS – Symmetrical Biphasic<br>TENS – Asymmetrical Biphasic<br>Russian<br>Direct Current<br>Microcurrent<br>High Voltage Pulsed Current (HVPC)<br>VMS, VMS Burst | N/A |
| **EMG (Biofeedback)** | no | yes | N/A |
| **TENS – asymmetrical biphasic** | | | |
| **Intensity – CC Mode** | 0–110 mA | 0–110 mA | N/A |
| **Intensity – CV mode** | 0–110 V | 0–110 V | N/A |
| **Maximum Phase Duration** | 20–1000 µs | 20–1000 µs | N/A |
| **Frequency Range** | 1–250 Hz | 0–250 Hz | N/A |

| Device Name | BTL-4000 | Vectra Genisys | Vectra Genisys Laser System |
|---|---|---|---|
| **Manufacturer** | BTL Industries, Inc. | Chattanooga Medical Supply, Inc. | Chattanooga Medical Supply, Inc. |
| **510(k) Number** | Current submission | K031077 | K040662 |
| **Maximum Average Power Density** | Electrode 7.5×14 cm ⟶ 0.05 W/cm$^2$<br>Electrode 3.2 cm ⟶ 0.62 W/cm$^2$<br>Electrode 5 cm ⟶ 0.25 W/cm$^2$ | - | N/A |
| **Current Density** | Depends on the surface of the chosen electrode 0.1–14 mA/cm$^2$ | Depends on the surface of the chosen electrode 0.1–16 mA/cm$^2$ | N/A |
| **Waveform Shape** |  |  | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500 V) | - | N/A |
| **TENS – symmetrical biphasic** | | | |
| **Intensity – CC Mode** | 0–80 mA | 0–80 mA | N/A |
| **Intensity – CV mode** | 0–80 V | 0–80 V | N/A |
| **Maximum Phase Duration** | 20–1000 µs | 20–1000 µs | N/A |
| **Frequency Range** | 1–250 Hz | 1–250 Hz | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm ⟶ 0.05 W/cm$^2$<br>Electrode 3.2 cm ⟶ 0.62 W/cm$^2$<br>Electrode 5 cm ⟶ 0.25 W/cm$^2$ | - | N/A |
| **Current Density** | Depends on the surface of the chosen electrode 0.1–10 mA/cm$^2$ | Depends on the surface of the chosen electrode 0.1–11.5 mA/cm$^2$ | N/A |
| **Waveform Shape** |  |  | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500 V) | - | N/A |
| **IFC - Interferential** | | | |
| **Intensity – CC Mode** | 0–100 mA | 0–100 mA | N/A |
| **Intensity – CV mode** | 0–100 V | 0–100 V | N/A |
| **Maximum Phase Duration** | - | - | N/A |
| **Frequency Range** | Carrier⟶2500, 4000 and 5000 Hz<br>Beat (sweep off)⟶1–200 Hz<br>Sweep Low Beat Frequency⟶1–199 Hz<br>Sweep High Beat Frequency⟶1–200Hz | Carrier⟶2500, 4000 and 5000 Hz<br>Beat (sweep off)⟶1–200 Hz<br>Sweep Low Beat Frequency⟶1–199 Hz<br>Sweep High Beat Frequency⟶1– 200 Hz | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm⟶0.05 W/cm$^2$<br>Electrode 3.2 cm⟶0.62 W/cm$^2$<br>Electrode 5 cm⟶0.25 W/cm$^2$ | - | N/A |
| **Current Density** | Depends on the surface of the chosen electrode 0.1–12.5 mA/cm$^2$ | Depends on the surface of the chosen electrode 0.1–14 mA/cm$^2$ | N/A |
| **Waveform Shape** |  |  | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500 V) | - | N/A |

| Device Name | BTL-4000 | Vectra Genisys | Vectra Genisys Laser System |
|---|---|---|---|
| **Manufacturer** | BTL Industries, Inc. | Chattanooga Medical Supply, Inc. | Chattanooga Medical Supply, Inc. |
| **510(k) Number** | Current submission | K031077 | K040662 |
| **Premodulated (2-pole Interference)** | | | |
| **Intensity – CC Mode** | 0–100 mA | 0–100 mA | N/A |
| **Intensity – CV mode** | 0–100 V | 0–100 V | N/A |
| **Maximum Phase Duration** | - | - | N/A |
| **Frequency Range** | Carrier⟶2500 Hz<br>Beat (sweep off)⟶1–200 Hz<br>Sweep Low Beat Frequency⟶1–199Hz<br>Sweep High Beat Frequency⟶2–200Hz | Carrier⟶2500 Hz<br>Beat (sweep off)⟶1–200 Hz<br>Sweep Low Beat Frequency⟶1–199Hz<br>Sweep High Beat Frequency⟶2–200Hz | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm⟶0.05 W/cm$^2$<br>Electrode 3.2 cm⟶0.62 W/cm$^2$<br>Electrode 5 cm⟶0.25 W/cm$^2$ | - | N/A |
| **Current Density** | 0.1–12.5 mA/cm$^2$ | 0.1–14 mA/cm$^2$ | N/A |
| **Waveform Shape** |  |  | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500 V) | - | N/A |
| **Russian Stimulation** | | | |
| **Intensity – CC Mode** | 0–100 mA | 0–100 mA | N/A |
| **Intensity – CV mode** | 0–100 V | 0–100 V | N/A |
| **Maximum Phase Duration** | - | - | N/A |
| **Frequency Range** | Carrier⟶2500 Hz<br>Burst frequency⟶20–100 bps | Carrier⟶2500 Hz<br>Burst frequency⟶20–100 bps | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm⟶0.05 W/cm$^2$<br>Electrode 3.2 cm⟶0.62 W/cm$^2$<br>Electrode 5 cm⟶0.25 W/cm$^2$ | - | N/A |
| **Current Density** | 0.1–12.5 mA/cm$^2$ | 0.1–14 mA/cm$^2$ | N/A |
| **Waveform Shape** |  |  | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500 V) | - | N/A |
| **Direct Current** | | | |
| **Intensity – CC Mode** | 0–4 mA | 0–4 mA | N/A |
| **Intensity – CV mode** | - | - | N/A |
| **Maximum Phase Duration** | 1–60s | - | N/A |
| **Frequency Range** | - | - | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm⟶0.05 W/cm$^2$<br>Electrode 3.2 cm⟶0.62 W/cm$^2$<br>Electrode 5 cm⟶0.25 W/cm$^2$ | - | N/A |
| **Current Density** | 0–0.5 mA/cm$^2$ | 0–0.6 mA/cm$^2$ | N/A |

| Device Name | BTL-4000 | Vectra Genisys | Vectra Genisys Laser System |
|---|---|---|---|
| **Manufacturer** | BTL Industries, Inc. | Chattanooga Medical Supply, Inc. | Chattanooga Medical Supply, Inc. |
| **510(k) Number** | Current submission | K031077 | K040662 |
| **Waveform Shape** |  |  | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500 V) | - | N/A |
| **Microcurrents** | | | |
| **Intensity – CC Mode** | 5–1000 µA | 5–1000 µA | N/A |
| **Intensity – CV mode** | - | - | N/A |
| **Maximum Phase Duration** | 0–1 s | - | N/A |
| **Frequency Range** | Carrier⟶0.1–1000 Hz | Carrier⟶0.1–1000 Hz | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm⟶0.05 W/cm$^2$<br>Electrode 3.2 cm⟶0.62 W/cm$^2$<br>Electrode 5 cm⟶0.25 W/cm$^2$ | - | N/A |
| **Current Density** | 0–0.12 mA/cm$^2$ | 0–0.14 mA/cm$^2$ | N/A |
| **Waveform Shape** | - | - | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500 V) | - | N/A |
| **High Voltage Pulsed Current (HVPC)** | | | |
| **Intensity – CC Mode** | - | - | N/A |
| **Intensity – CV mode** | 0–500 V | 0–500 V | N/A |
| **Maximum Phase Duration** | 50 µs | - | N/A |
| **Frequency Range** | 10–120 pps | 10–120 pps | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm⟶0.05 W/cm$^2$<br>Electrode 3.2 cm⟶0.62 W/cm$^2$<br>Electrode 5 cm⟶0.25 W/cm$^2$ | - | N/A |
| **Waveform Shape** |  |  | N/A |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500V) | - | N/A |
| **VMS, VMS Burst** | | | |
| **Intensity – CC Mode** | 0–200 mA | 0–200 mA | N/A |
| **Intensity – CV mode** | 0–200 V | 0–200 V | N/A |
| **Maximum Phase Duration** | 20–400 µs | 20–400 µs | N/A |
| **Frequency Range** | 1–200 Hz | 1–200 Hz | N/A |
| **Maximum Average Power Density** | Electrode 7.5×14 cm⟶0.05 W/cm$^2$<br>Electrode 3.2 cm⟶0.62 W/cm$^2$<br>Electrode 5 cm⟶0.25 W/cm$^2$ | - | N/A |
| **Current Density** | 0.1–25 mA/cm$^2$ | 0.1–30 mA/cm$^2$ | N/A |
| **Waveform Shape** |  |  | N/A |

| Device Name | BTL-4000 | Vectra Genisys | Vectra Genisys Laser System |
|---|---|---|---|
| **Manufacturer** | BTL Industries, Inc. | Chattanooga Medical Supply, Inc. | Chattanooga Medical Supply, Inc. |
| **510(k) Number** | Current submission | K031077 | K040662 |
| **Electrode Size** | 7.5×14 cm<br>3.2 cm<br>5 cm | 3 cm<br>7 cm | N/A |
| **Number of Channels** | 2 | 2 | N/A |
| **Channel Isolation** | 1 MOPP (1500V) | - | N/A |
| **Laser Module** | | | |
| **Electrical protection** | BF | N/A | B |
| **Frequency** | 8–10000 Hz and continuous | N/A | 8–10000 Hz and continuous |
| **Type of applicators** | probe, cluster | N/A | probe, cluster |
| **Laser applicators models** | Probe 830 nm/50 mW<br>Probe 830 nm/100 mW<br>Probe 830 nm/200 mW<br>Probe 830 nm/300 mW<br><br>Laser cluster⟶685 nm/200 mW<br>Laser cluster⟶830 nm/800 mW<br>Laser cluster⟶830 nm/1300 mW<br>Combined cluster⟶685 nm, 830 nm/1000 mW<br>Combined cluster⟶685 nm, 830 nm/1500 mW | N/A | 850 nm/100 mW<br>850 nm/150 mW<br>850 nm/200 mW<br>820 nm/300 mW<br><br>670 nm, 950 nm Cluster 540 mW<br><br>670 nm, 950 nm Cluster 1040 mW<br><br>670 nm,850 nm, 950 nm Cluster 415 mW<br><br>670 nm,850 nm, 950 nm Cluster 715 mW<br><br>670 nm, 850 nm, 880 nm, 950 nm Cluster 1440 mW |
| **Applicators** | single diode applicator 0.0314 $cm^2$<br>cluster 25 $cm^2$ | N/A | single diode applicator 0.07–0.495 $cm^2$<br>cluster 7.55–31.2 $cm^2$ |
| **Output Power** | 5–1500 mW (dependent on applicator) | N/A | 100–1440 mW (dependent on applicator) (± 20%) |
| **Duty cycle setting** | yes | N/A | yes |
| **Wavelength** | 685–830 nm (± 20%) | N/A | 670–950 nm |
| **Ultrasound Module** | | | |
| **Electrical Protection** | Class II, BF | Class I, B | N/A |
| **Intensity – Continuous Mode** | 0.1–2 W/$cm^2$ (± 30%) | 0–2.5 W/$cm^2$ | N/A |
| **Intensity – Pulsed Mode** | 0.1–3 W/$cm^2$ (± 30%) | 0–3 W/$cm^2$ | N/A |
| **Frequency** | 1 MHz (± 5%) | 1 MHz (± 5%) | N/A |
| | 3.1 MHz (± 5%) | 3.3 MHz (± 5%) | N/A |
| **Duty Cycle** | 6.25–100 % (± 30%) | 10%, 20%, 50%, Continuous | N/A |
| **Pulse Frequency** | 10–100 Hz | 100 Hz | N/A |
| **Ultrasound Heads** | 1 $cm^2$, 5 $cm^2$, Handsfree Sono 4, Handsfree Sono 6 | 1 $cm^2$, 2 $cm^2$, 5 $cm^2$, 10 $cm^2$ | N/A |
| **Applicator Size 1 $cm^2$ Head** | Crystal diameter – 1.25 cm<br>Surface – 1.5 $cm^2$ | 1 $cm^2$ | N/A |
| **Applicator Size 5 $cm^2$ Head** | Crystal diameter – 2.5 cm<br>Surface – 7.9 $cm^2$ | 5 $cm^2$ | N/A |
| **Applicator Size Handsfree Sono 4** | Crystal – 3×1.4 cm<br>Surface of the applicator – 31.5 $cm^2$ | - | N/A |

| Device Name | BTL-4000 | Vectra Genisys | Vectra Genisys Laser System |
|---|---|---|---|
| **Manufacturer** | BTL Industries, Inc. | Chattanooga Medical Supply, Inc. | Chattanooga Medical Supply, Inc. |
| **510(k) Number** | Current submission | K031077 | K040662 |
| **Applicator Size Handsfree Sono 6** | Crystal – 2.4×1.7 cm<br>Surface of the applicator – 31.5 $cm^2$ | - | N/A |
| **Applicator Size 2 $cm^2$ Head** | - | 2 $cm^2$ | N/A |
| **Applicator Size 10 $cm^2$ Head** | - | 10 $cm^2$ | N/A |
| **Crystal Material** | • USN 1 $cm^2$⟶Pz26<br>• USN 5 $cm^2$⟶Pz26<br>• HandsFree 4⟶piezoceramic NCE41<br>• HandsFree 6⟶piezoceramic NCE41 | - | N/A |
| **Beam Type** | collimated<br>1 $cm^2$ head⟶1MHz divergent beam | collimated | N/A |
| **Temporal Max Power for Pulsed Mode** | • USN 1 $cm^2$⟶2.7 W ±20 %<br>• USN 5 $cm^2$⟶13.2 W ±20 %<br>• HandsFree 4⟶12.3 W ±20 %<br>• HandsFree 6⟶12.3 W ±20 % | • USN 1 $cm^2$⟶3 W ±20 %<br>• USN 2 $cm^2$⟶6 W ±20 %<br>• USN 5 $cm^2$⟶15 W ±20 %<br>• USN 10 $cm^2$⟶30 W ±20 % | N/A |
| **Temporal Average Power for Continuous Mode** | • USN 1 $cm^2$⟶1.8 W ±20 %<br>• USN 5 $cm^2$⟶8.8 W ±20 %<br>• HandsFree 4⟶8.2 W ±20 %<br>• HandsFree 6⟶8.2 W ±20 % | • USN 1 $cm^2$⟶2.5 W ±20 %<br>• USN 2 $cm^2$⟶5 W ±20 %<br>• USN 5 $cm^2$⟶7.5 W ±20 %<br>• USN 10 $cm^2$⟶25 W ±20 % | N/A |
| **Instantaneous Peak Power** | • USN 1 $cm^2$⟶2.7 W ±20 %<br>• USN 5 $cm^2$⟶13.2 W ±20 %<br>• HandsFree 4⟶12.3 W ±20 %<br>• HandsFree 6⟶12.3 W ±20 % | • USN 1 $cm^2$⟶3 W ±20 %<br>• USN 2 $cm^2$⟶6 W ±20 %<br>• USN 5 $cm^2$⟶15 W ±20 %<br>• USN 10 $cm^2$⟶30 W ±20 % | N/A |
| **Temporal Max Effective Intensity, peak P/ERA** | 3 W/$cm^2$ ±30 % | 3 W/$cm^2$ ±20 % | N/A |
| **Temporal Average Intensity** | 0.1–2 W/$cm^2$ ±30 % for the output intensity higher than 0.2 W/$cm^2$ | 0.1–2 W/$cm^2$ ±20 % | N/A |
| **Temporal Peak to Average Ratio (Rtpa) for Pulsed Mode** | 16:1; 8:1; 4:1; 2:1; 1:1 | 2:1 ±20% at 50% duty cycle<br>5:1 ±20% at 20% duty cycle<br>10:1 ±20% at 10% duty cycle | N/A |
| **Error Uncertainties for the Ultrasonic Frequency** | ±5 % | ±5 % | N/A |
| **Effective radiating Area and Accuracy (Beam Cross Section)** | • USN 1 $cm^2$⟶0.9 $cm^2$ ±20 %<br>• USN 5 $cm^2$⟶4.4 $cm^2$ ±20 %<br>• HandsFree 4⟶4×4.1 $cm^2$ ±20 %<br>• HandsFree 6⟶6×4.1 $cm^2$ ±20 % | • USN 1 $cm^2$⟶0.7–1 $cm^2$<br>• USN 2 $cm^2$⟶1.4–2 $cm^2$<br>• USN 5 $cm^2$⟶3.5–5 $cm^2$<br>• USN 10 $cm^2$⟶6.8–10 $cm^2$ | N/A |
| **HandsFree Sono Applicators** | • Applicator mode – circular/random (switching between crystals)<br>• Switching period – 0.3 s/0.5 s/0.7 s<br>• Application area – activation/deactivation of crystal pairs (at least one pair)<br>(for safety reasons when you choose one pair of crystals the switching period is fixed to 0.3 s) | N/A | N/A |
| **Covering Grade** | IP67 | IPX7 | N/A |
| **Contact Monitoring** | yes | yes | N/A |
| **Head Preheating** | yes | yes | N/A |

## Substantial Equivalence

Based upon the intended use and technical information provided in this pre-market notification, the BTL-4000 device has been shown to be substantially equivalent to currently marketed predicate devices.

## Conclusion

Based on the aforementioned information, the BTL-4000 is safe and effective and substantially equivalent to the identified predicate devices.