November 21, 2023

Belega Inc.
% Nana Nagashita
Regulatory Consultant
Ken Block Consulting Co., Ltd.
1-9-9 Tsukiji
Chuo-ku, Tokyo 104-0045
Japan

Re: K233010
Trade/Device Name: Beagank 4T Plus
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: September 15, 2023
Received: September 22, 2023

Dear Nana Nagashita:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Heather L. Dean -S

Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
DHT5B: Division of Neuromodulation
and Rehabilitation Devices

OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

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)*
K233010

Device Name
BEAGANK 4T PLUS

Indications for Use *(Describe)*
The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.

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.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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**510(k) SUMMARY**

| | | |
|---|---|---|
| Owner/Submitter: | Belega Co., Ltd.<br>1-4-20 Sonezaki Shinchi, Kita-ku<br>Osaka-shi, Osaka, Japan 530-0002 | |
| Contact Person: | Ken Block Consulting Co., Ltd.<br>Ms. Nana Nagashita<br>Regulatory consultant<br><br>1-9-9 Tsukiji, Chuo-ku<br>Tokyo, Japan 104-0045<br>TEL: +81-3-6260-6688<br>FAX: +81-3-6260-6689<br>nagashita@kenblockconsulting.com | |
| Date Prepared: | September 20, 2023 | |
| Submission Type: | Traditional 510(k) | |
| Proposed Device | Manufacturer:<br>Trade Name:<br>Common Name:<br>Classification Name:<br>Product Code:<br><br>Regulatory Standard | BELEGA Co., Ltd.<br>BEAGANK 4T PLUS<br>Aesthetic TENS Device<br>Transcutaneous Electrical Nerve Stimulator for Pain Relief<br>NFO<br><br>21 CFR 882.5890 |
| Predicate Device: | 510(k) Number:<br>Manufacturer:<br>Trade Name:<br><br>Common Name:<br>Classification Name:<br>Product Code<br>Regulatory Standard: | K191951<br>Avazzia, Inc.<br>Avazzia OTC TENS for Aesthetics, model BEST-AV1: EZZI-LIFT Device<br>Aesthetic TENS Device<br>Transcutaneous Electrical Nerve Stimulator for Pain Relief<br>NFO<br>21 CFR 882.5890 |
| Reference Device: | 510(k) Number:<br>Manufacturer:<br>Trade Name:<br><br>Common Name:<br>Classification Name:<br>Product Code:<br>Regulatory Standard: | K011935<br>Salton Inc.<br>Rejuvenique® system, Model RJV-10<br><br>Aesthetic TENS Device<br>Transcutaneous Electrical Nerve Stimulator for Pain Relief<br>NFO, GYB (Media, Conductive)<br>21 CFR 882.5890, 21 CFR 882.1275 (Media, Conductive) |
| Reference Device: | 510(k) Number:<br>Manufacturer:<br>Trade Name:<br>Common Name:<br>Classification Name:<br>Product Code:<br>Regulatory Standard: | K181008<br>Carol Cole Company dba NuFACE<br>NuFACE Trinity<br>Aesthetic TENS Device<br>Transcutaneous Electrical Nerve Stimulator for Pain Relief<br>NFO<br>21 CFR 882.5890 |

Device Description: BEAGANK 4T PLUS is a cosmetic device which is intended for use on the face and body skin. The device contains a rechargeable lithium ion battery and is provided with a charger. The device has four electrode metal pads on the head that deliver electrical impulses to the face and body skin and provide four different operational modes.

The device operates by applying Transcutaneous Electrical Nerve Stimulation to the face and body skin. The electrodes that are positioned on the skin must be covered with a wet cotton pad. Purified water or commercially available cosmetic formulation liquid can be used as a conductive media to generate the electric pulses. Two attachments are provided with the BEAGANK 4T PLUS:

- Scalp attachment
- Small attachment

Statement of Intended Use: The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation.

Summary of Technological Characteristics: The major differences between the proposed and predicate devices are summarized in the tables below:

**Table 1: Basic characteristics**

| | New Device | Predicate Device | Reference Device | Reference Device |
|---|---|---|---|---|
| Trade Name | BEAGANK 4T PLUS | EZZI-LIFT Device | Rejuvenique | NuFACE Trinity |
| 510(k) | K233010 | K191951 | K011935 | K181008 |
| Indication for Use | The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | Rejuvenique system is indicated for cosmetic use. | The NuFACE Trinity is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use. |
| Device Class | Class II | Class II | Class II | Class II |
| Operating Power | Internal rechargeable Lithium-ion battery | Two 1.5 V AA batteries | 9 V battery | Internal rechargeable Lithium-ion battery |
| Method of Line Current Isolation | Type BF | Unknown | Unknown | Type BF |

| | | | | | |
|---|---|---|---|---|---|
| Patient Leakage Current | Normal | DC: <1µA<br>AC: <1µA<br>Tested per IEC 60601-1 | Unknown | Unknown | N/A – Battery operated |
| | Single fault | DC: <1µA<br>AC: <1µA<br>Tested per IEC 60601-1 | Unknown | Unknown | N/A – Battery operated |
| Ave. DC current through electrodes when device is on but no pulse are being applied (µA) | | < 1µA | Unknown | Unknown | Unknown |
| Output Channels | Method of Channel Isolation | N/A – 1 output channel | Unknown | Electrode group selected by relays | N/A – 1 output channel |
| Regulated Current or Regulated Voltage | | Voltage | Unknown | Voltage | Both |
| Automatic Overload Trip | | Not required due to circuit design | Unknown | No | Not required due to circuit design |
| Automatic No-Load Trip | | Not required due to circuit design | Unknown | No | Yes |
| Automatic Shut Off | | Yes | Yes | Yes | Yes |
| Patient Override Control | | Yes | Unknown | Yes | Yes |
| Weight | | 136g | 153g<br>(5.4 ounces) | 80 g | 9 oz. without charging base |
| Number of output modes | | 4 modes: maximum 5 minutes each | 4 modes: 60 minutes | 1 | Unknown |
| Low Battery Indicator | | Yes | Yes | Yes | Yes |
| Sterility | | Non-Sterile | Non-Sterile | Non-Sterile | Non-Sterile |
| Electrical safety | | - IEC 60601-1 Medical electrical equipment – Part 1 General requirements for basic safety and essential performance<br>- IEC 60601-1-2 Medical electrical equipment – | - IEC 60601-1 Medical electrical equipment – Part 1 General requirements for safety<br>- IEC 60601-1-2 Medical electrical equipment – Part 1-2: General requirements | Unknown | - IEC 60601-1<br>- IEC 60601-1-2 |

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|---|---|---|---|---|
| | Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests | for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests<br>- IEC 60601-2-10 medical electrical equipment – Part 2:10; Particular requirements for the safety of nerve and muscle stimulators | | |
| Housing Materials and Construction | ABS | PCBs inside plastic case housing | ABS Plastic, snap latch assembly | Thermoplastic |
| Accessories | Small and Scalp attachment | Built-in, Y, Brush, Pencil | Unknown | Unknown |

**Table 2: Technological Characteristics**

| Output Specifications: **Mode 1** | | | | |
|---|---|---|---|---|
| | **New Device** | Predicate Device | Reference Device | Reference Device |
| Trade Name | BEAGANK 4T PLUS | EZZI-LIFT Device | Rejuvenique | NuFACE Trinity |
| Indications for Use | The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | Rejuvenique system is indicated for cosmetic use. | The NuFACE Trinity is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use. |

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| Waveform Shape | Rectangle, biphasic asymmetric | Positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading | Pulsed biphasic, Rectangular (+phase), Spike (-phase) | Pulsed biphasic modulated square wave |
| Max output voltage<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>127mV (0.12V)<br>515mV (0.51V)<br>1.83V | (+/-20%)<br>-42V<br>-122V<br>-348V | (+/-10%)<br>18.8V<br>24.8V<br>28.0V | 28VDC<br>not publicly available<br>not publicly available |
| Max output current<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>0.19mA<br>0.18mA<br>0.16mA | (+/-20%)<br>363µA(0.363 mA)<br>117µA (0.117 mA)<br>38µA (0.038 mA) | (+/-10%)<br>37.6mA<br>12.4mA<br>2.8mA | 400µA (0.4mA)<br>not publicly available<br>not publicly available |
| Duration of primary pulse at 500Ω | Positive: 130µs (0.13msec)<br>Negative: 130µs (0.13msec) | 0.5msec | not publicly available | 60msec |
| Pulse Duration (Cycle) at 500Ω | 265µs (0.265msec) | 1.1msec | 300msec (+phase)<br>124.7msec (-phase, exponential) | 60msec |
| Frequency | 3.80kHz | 15-121Hz | 8Hz fixed | 8.3Hz |
| Net Charge per pulse at 500Ω | 0.025µC | 4µC | 0µC | not publicly available |
| Max phase charge | 0.059µC | 10µC | 11.3µC | not publicly available |
| Max current density at 500Ω | - Standard: 0.15mA/$cm^2$<br>- Scalp: 0.53mA/$cm^2$<br>- Small: | Built-in, Y, Brush: 800µA/$cm^2$(0.80mA/$cm^2$) | 46.4mA/$cm^2$ | not publicly available |

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| | 1.36mA/cm$^2$<br><br>With a wet cotton pad (Purified water)<br>- Standard:0.15 mA/cm$^2$<br>- Scalp: 0.53mA/cm$^2$<br>Small: 1.36mA/cm$^2$ | Pencil: 19,000μA/cm$^2$ (19mA/cm$^2$) | | |
| Max power density at 500Ω (Smallest electrode) | - 8.51μW/cm$^2$<br>- With a wet cotton pad 11.39μW/cm$^2$ | Built-in, Y, Brush: Average 500μW/cm$^2$<br><br>Pencil: Average 3,500μW/cm$^2$ | 2.31mW/cm$^2$<br><br>(2,310μW/cm$^2$) | not publicly available |
| Max. Average Current (mA) | 0.105 | not publicly available | not publicly available | not publicly available |
| Burst mode | | | | |
| Pulse per burst | N/A | N/A | 160 | 20 |
| Burst per second | N/A | N/A | 1/240 (per electrode group) | 8.3 |
| Burst duration | N/A | N/A | 20sec | 2.4 |
| Duty cycle | N/A | N/A | 1/12 | 20.2sec |
| On Time (seconds) | N/A | N/A | 20sec/electrode group | not publicly available |
| Off Time (seconds) | N/A | N/A | not publicly available | not publicly available |
| Output Specifications: **Mode 2** | | | | |
| | **New Device** | Predicate Device | Reference Device | Reference Device |
| Trade Name | BEAGANK 4T PLUS | EZZI-LIFT Device | Rejuvenique | NuFACE Trinity |
| Indications for Use | The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and | The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over- | Rejuvenique system is indicated for cosmetic use. | The NuFACE Trinity is intended for facial and neck stimulation and is indicated for over- |

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| | neck stimulation or body skin stimulation. | the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | | the-counter cosmetic use. |
| Waveform Shape | Rectangle, biphasic asymmetric | Positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading | Pulsed biphasic, Rectangular (+phase), Spike (-phase) | Pulsed biphasic modulated square wave |
| Max output voltage<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>110mV (0.11V)<br>507mV (0.50V)<br>1.87V | (+/-20%)<br>-42V<br>-122V<br>-348V | (+/-10%)<br>18.8V<br>24.8V<br>28.0V | 28VDC<br>not publicly available<br>not publicly available |
| Max output current<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>0.45mA<br>0.39mA<br>0.24mA | (+/-20%)<br>363µA (0.363mA)<br>117µA (0.117mA)<br>38µA (0.038mA) | (+/-10%)<br>37.6mA<br>12.4mA<br>2.8mA | 400µA (0.4mA)<br>not publicly available<br>not publicly available |
| Duration of primary pulse at 500Ω | Positive: 130µs (0.13msec)<br>Negative: 130µs (0.13msec) | 0.5msec | not publicly available | 60msec |
| Pulse Duration (Cycle) at 500Ω | 265µs (0.265msec) | 1.1msec | 300msec (+phase)<br>124.7msec (-phase, exponential) | 60msec |
| Frequency | 3.80kHz | 15-121Hz | 8Hz fixed | 8.3Hz |
| Net Charge per pulse at 500Ω | 0.025µC | 4µC | 0µC | not publicly available |

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| Max phase charge | 0.025μC | 10μC | 11.3μC | not publicly available |
| Max current density at 500Ω | - Standard: 0.36mA/ $cm^2$<br>- Scalp: 1.25mA/$cm^2$<br>- Small: 3.21mA/$cm^2$ | Built-in, Y, Brush: 800μA/$cm^2$ (0.8mA/$cm^2$)<br><br>Pencil: 19,000μA/$cm^2$ (19mA/$cm^2$) | 46.4mA/$cm^2$ | not publicly available |
| | With a wet cotton pad (Purified water)<br><br>- Standard: 0.10mA/$cm^2$<br>- Scalp: 0.36 mA/$cm^2$<br>Small: 0.92 mA/$cm^2$ | | | |
| Max power density at 500Ω (Smallest electrode) | - 17.46μW/$cm^2$ | Built-in, Y, Brush: Average 500μW/$cm^2$<br><br>Pencil: Average 3,500μW/$cm^2$ | 2.31mW/$cm^2$<br><br>(2,310μW/$cm^2$) | not publicly available |
| | - With a wet cotton pad 33.87μW/$cm^2$ | | | |
| Max. Average Current (mA) | 0.105 | not publicly available | not publicly available | not publicly available |
| Burst mode | | | | |
| Pulse per burst | N/A | N/A | 160 | 20 |
| Burst per second | N/A | N/A | 1/240 (per electrode group) | 8.3 |
| Burst duration | N/A | N/A | 20sec | 2.4 |
| Duty cycle | N/A | N/A | 1/12 | 20.2sec |
| On Time (seconds) | N/A | N/A | 20sec/electrode group | not publicly available |
| Off Time (seconds) | N/A | N/A | not publicly available | not publicly available |
| Output Specifications: **Mode 3** | | | | |
| | **New Device** | Predicate Device | Reference Device | Reference Device |

| Trade Name | BEAGANK 4T PLUS | EZZI-LIFT Device | Rejuvenique | NuFACE Trinity |
|---|---|---|---|---|
| Indications for Use | The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | Rejuvenique system is indicated for cosmetic use. | The NuFACE Trinity is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use. |
| Waveform Shape | Rectangle, biphasic symmetrical | Positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading | Pulsed biphasic, Rectangular (+phase), Spike (-phase) | Pulsed biphasic modulated square wave |
| Max output voltage<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>16.6V<br>21.0V<br>22.5V | (+/-20%)<br>-42<br>-122<br>-348 | (+/-10%)<br>18.8V<br>24.8V<br>28.0V | 28VDC<br>not publicly available<br>not publicly available |
| Max output current<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>30.8mA<br>8.52mA<br>2.26mA | (+/-20%)<br>363µA(0.363 mA)<br>117µA (0.117 mA)<br>38µA (0.038 mA) | (+/-10%)<br>37.6mA<br>12.4mA<br>2.8mA | 400µA<br>not publicly available<br>not publicly available |
| Duration of primary pulse at 500Ω | Positive: 80µs (0.08msec)<br>Negative: 80µs (0.08msec) | 0.5msec | not publicly available | 60msec |
| Pulse Duration (Cycle) at 500Ω | 274µs (0.247msec) | 1.1msec | 300msec (+phase)<br>124.7msec (-phase, exponential) | 60msec |

| | | | | |
|---|---|---|---|---|
| Frequency | 3.65kHz | 15-121Hz | 8Hz fixed | 8.3Hz |
| Net Charge per pulse at 500Ω | -1.3μC | 4μC | 0μC | not publicly available |
| Max phase charge | 2.2μC | 10μC | 11.3μC | not publicly available |
| Max current density at 500Ω | - Standard: 24.4mA/ $cm^2$<br>- Scalp: 85.6mA/$cm^2$<br>- Small: 220 mA/$cm^2$ | Built-in, Y, Brush: 800μA/$cm^2$ (0.8mA/$cm^2$)<br><br>Pencil: 19,000μA/$cm^2$ (19mA/$cm^2$) | 46.4mA/$cm^2$ | not publicly available |
| | With a wet cotton pad (Purified water)<br><br>- Standard: 4.26mA/ $cm^2$<br>- Scalp: 28.21mA/$cm^2$<br>Small: 38.43mA/$cm^2$ | | | |
| Max power density at 500Ω (Smallest electrode) | - 106638.40μW/$cm^2$ | Built-in, Y, Brush: Average 500μW/$cm^2$<br><br>Pencil: Average 3,500μW/$cm^2$ | 2.31mW/ $cm^2$ (2,310μW/$cm^2$) | not publicly available |
| | - With a wet cotton pad 1124.0μW/$cm^2$ | | | |
| Max. Average Current (mA) | 0 | not publicly available | not publicly available | not publicly available |
| Burst mode | | | | |
| Pulse per burst | N/A | N/A | 160 | 20 |
| Burst per second | N/A | N/A | 1/240 (per electrode group) | 8.3 |
| Burst duration | N/A | N/A | 20sec | 2.4 |
| Duty cycle | N/A | N/A | 1/12 | 20.2sec |

| | | | | |
|---|---|---|---|---|
| On Time (seconds) | N/A | N/A | 20sec/electrode group | not publicly available |
| Off Time (seconds) | N/A | N/A | not publicly available | not publicly available |
| Output Specifications: **Mode 4** | | | | |
| | **New Device** | Predicate Device | Reference Device | Reference Device |
| Trade Name | BEAGANK 4T PLUS | EZZI-LIFT Device | Rejuvenique | NuFACE Trinity |
| Indications for Use | The BEAGANK 4T PLUS is a handheld portable device for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | The Avazzia OTC TENS for aesthetics, model BEST-AV1™: EZZI-LIFT™ Device is indicated for over-the-counter aesthetic use including facial and neck stimulation or body skin stimulation. | Rejuvenique system is indicated for cosmetic use. | The NuFACE Trinity is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use. |
| Waveform Shape | Rectangle,<br>Biphasic symmetric | Positive square wave followed by a damped sinusoidal waveform of variable duration depending on damping and body loading | Pulsed biphasic, Rectangular (+phase), Spike (-phase) | Pulsed biphasic modulated square wave |
| Max output voltage<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>15.3V<br>21.2V<br>22.9V | (+/-20%)<br>-42V<br>-122V<br>-348V | (+/-10%)<br>18.8V<br>24.8V<br>28.0V | 28VDC<br>not publicly available<br>not publicly available |
| Max output current<br>@500Ω<br>@2kΩ<br>@10kΩ | (+/-15%)<br>31.4mA<br>8.60mA<br>2.15mA | (+/-20%)<br>363µA(0.363 mA)<br>117µA (0.117 mA)<br>38µA (0.038 mA) | (+/-10%)<br>37.6mA<br>12.4mA<br>2.8mA | 400µA<br>not publicly available<br>not publicly available |

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|---|---|---|---|---|
| Duration of primary pulse at 500Ω | Positive: 92µs (0.092msec)<br><br>Negative: 92µs (0.092msec) | 0.5msec | not publicly available | 60msec |
| Pulse Duration (Cycle) at 500Ω | 610µs (0.61msec) | 1.1msec | 300msec (+phase)<br>124.7msec (-phase, exponential) | 60msec |
| Frequency | 1.64kHz | 15 to 121 Hz | 8 Hz fixed | 8.3Hz |
| Net Charge per pulse at 500Ω | 0µC (biphasic<br><br>symmetrical) | 4µC | 0µC | not publicly available |
| Max phase charge | 0.29µC | 10µC | 11.3µC | not publicly available |
| Max current density at 500Ω | - Standard: 25.0mA/ $cm^2$<br>- Head: 87.2mA/$cm^2$<br>Small: 224.3mA/$cm^2$ | Built-in, Y, Brush: 800µA/$cm^2$ (0.8mA/$cm^2$)<br><br>Pencil: 19,000µA/ $cm^2$(19mA/$cm^2$) | 46.4 mA/$cm^2$ | not publicly available |
| | With a wet cotton pad (Purified water)<br><br>- Standard: 3.13mA/$cm^2$<br>- Scalp: 10.97mA/$cm^2$<br>Small:28.21mAW/c $m^2$ | | | |
| Max power density at 500Ω (Smallest electrode) | - 51775.54µW/c $m^2$ | Built-in, Y, Brush: Average 500µW/$cm^2$<br><br>Pencil: Average 3,500µW/$cm^2$ | 2.31mW/$cm^2$<br><br>(2,310µW/$cm^2$) | not publicly available |
| | - With a wet cotton pad 556.96µW/$cm^2$ | | | |
| Max. Average Current (mA) | 0 | not publicly available | not publicly available | not publicly available |
| Burst mode | | | | |
| Pulse per burst | N/A | N/A | 160 | 20 |

| | | | | |
|---|---|---|---|---|
| Burst per second | N/A | N/A | 1/240 (per electrode group) | 8.3 |
| Burst duration | N/A | N/A | 20sec | 2.4 |
| Duty cycle | N/A | N/A | 1/12 | 20.2sec |
| On Time (seconds) | N/A | N/A | 20sec/electrode group | not publicly available |
| Off Time (seconds) | N/A | N/A | not publicly available | not publicly available |

Clinical Test Data: No new clinical studies have been submitted as part of this Premarket Notification.

Summary of Non-Clinical / Test Data: Tests were performed on the device which demonstrated that the device is safe and effective, performs comparably to and is substantially equivalent to the predicate device.

Testing confirmed that the device complies with safety standards for Electrical Safety and Electromagnetic Compatibility testing, specifically IEC standards 60601-1 and 60601-1-2.

Testing confirmed that the device electrodes complies with safety standards for Biocompatibility testing, specifically ISO standards 10993-5, 10993-10, and 10993-23.

Conclusion: Company considers the BEAGANK 4T PLUS device to be substantially equivalent to the predicate device and reference devices listed above. This conclusion is based on the similarities in primary intended use, principles of operation, functional design, and established medical use.