April 27, 2023

Johari Digital Healthcare Limited
Pooja Johari
Founder and Director Marketing
G-582, 584 EPIP, Boranda
Jodhpur, Rajasthan 342012
India

Re: K213078
Trade/Device Name: Myolift QT
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: March 24, 2023
Received: March 27, 2023

Dear Pooja Johari:

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,

Tushar Bansal -S

for Heather Dean, PhD
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)*
K213078

Device Name
Myolift QT

Indications for Use *(Describe)*
"Myolift QT" is indicated for facial and neck stimulation and is indicated for over-the-counter cosmetic use.

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

510 (k) Summary
As required by 21 CFR 807.92(c)

Device Name	Myolift QT
Submitters name /contact details	Nisha Johari Johari Digital Healthcare Ltd G-582, 584 EPIP, Boranada, Jodhpur – India – 342008 Contact number: +1 (818)-521-8947
Summary Preparation Date	06-Jan-23
Device Trade Name	Myolift QT
Classification Name	**Transcutaneous Electrical Nerve Stimulator for Pain Relief**
Classification Regulation	21CFR 882.5890, Class II
Classification Product Code	NFO

Legally marketed Predicate Device

Device Trade Name	ZIIP+ Device
Classification Name	Transcutaneous electrical nerve stimulator for pain relief
510(K) No	K212342
Address and Registration	ZIIP, Inc. 1910 15th Ave E Seattle, Washington 98112
FDA Registration	3012050654

Device Description

The MyoliftQT is a microcurrent, handheld, and mobile application-based device which is easy to operate. The mobile application used in the device supports both types of users (iPhone®/Android™). The user has to download the application via Google Play™ store (Android) /App Store® (IOs) and connect the device via Bluetooth of their phone. The users can thereafter make their profiles accordingly.

The purpose of this device is to lift and tone the face and neck. It is a battery-powered device used with conductive gel. The conductive gel is used to reduce the impedance between the electrodes and the skin of the user.

Myolift QT has one channel and two output ports. One output is through the applicator ball and the other output is through the lead wire via the USB port connected through the charging port.

The Lead wire is connected to the device via USB. And electrodes are connected through the lead wire to give skin treatment to the user. The Metal balls and the electrodes are in contact with the user/patient maximum of 60 min, therefore the Surface-contacting, less than 24-hour duration.

The Sphere shape applicator balls made up of stainless steel in this device are designed to gently roll over the skin to deliver low-level electrical impulses in the face and neck region. The device delivers current in the range of 350 microamperes and low 160-microampere current.

Note: During treatment, only one output port works.

In skin treatment, the device minimize the fine lines and wrinkles on the skin.

This device delivers two types of waveforms (Erase and Educate) for effective skincare treatment.

It is intended to be used by multiple users (multiple applications). The device can be switched ON|OFF by simple touch on the power button.

The device offers multiple LED indications (Visual) to indicate the different states of the device.

- A flashing blue LED light indicates that the device is ON|OFF and when the device is connected to Bluetooth, the flashing blue light becomes steady.
- A Red LED indicates battery low while A Green LED indicates the chagrining of the device

It is a portable device having dimensions 6.65” x 1.85” x 1.49” [L X B X H]. Its outer case is made up of thermoplastic resin. The device comes with a C-type USB cable for the charging of the device. The device is automatically turned off if it is not connected via Bluetooth or not operated for more than 10 minutes.

Myolift QT comes with the necessary components. Below is a list of items that are included:

S. No.	Particular	Quantity
1	User Manual	1No.
2	Lead Wire with C type connector 1.5 Meter	1No.
3	Eye mask **(Adhesive Electrodes)**	1No.
4	Lip mask **(Adhesive Electrodes)**	1No.
5	Forehead Mask **(Adhesive Electrodes)**	1No.
6	Conductive Gloves	1 Pair
7	USB Cable Type C	1No.
8	Adaptor (Optional) I/p- 100-240V, 0.3A, O/p 5.0V, 2.1A , UL approved (E317867)	1No.

Indications for Use

"**Myolift QT**" is indicated for facial and neck stimulation and is indicated for over-the-counter cosmetic use.

Comparison of Technological Characteristics

A comparison given below identifies all the changes between the modified and the predicate device:

Basic Device Characteristics – Comparison with Predicate Device

Feature	New Device	Predicate Device	Comparison
Device Name	**Myolift QT**	ZIIP+ Device	-
510 (k)	**K213078**	K212342	-
OTC/Rx	OTC	OTC	Identical
Manufactured By	Johari Digital Healthcare Ltd.	ZIIP, LLC	-
Regulation Number	21CFR, Part 882.5890	21CFR, Part 882.5890	Identical
Product Code	NFO	NFO	Identical
Common Name	Transcutaneous Electrical Nerve Stimulator	Transcutaneous Electrical Nerve Stimulator	Identical
Indications for Use /Intended Use	"**Myolift QT**" is indicated for facial and neck stimulation and is indicated for over-the-counter cosmetic use.	The ZIIP+ Device is intended for facial and neck stimulation and is indicated for over-the-counter cosmetic use.	Identical
Mechanism of Action	Microcurrent electrical therapy to deliver skin stimulation through cellular response	Microcurrent electrical therapy to deliver skin stimulation through cellular response	Identical
Power Source	Internal Rechargeable Lithium-Ion Battery,	Internal Rechargeable Lithium-Ion Battery,	Identical
Type of Energy	Electrical current	Electrical current	Identical
Number of Outputs Synchronous or Alternating?	1+1 Alternating	N/A – 1 Output Channel	Identical
Method of Line Current Isolation	Rechargeable Lithium-ion battery and external charger isolation	One Rechargeable Lithium-Ion Battery, and External Charger Isolation	Identical
Patient Leakage Current Normal condition Single Fault condition	External Charger Included Normal Condition - 46µA Single Fault Condition- 46 µA	External Charger Included Normal Condition - 46µA Single Fault Condition- 46 µA	Identical
Method of Channel Isolation	N/A – 1 Output Channel	N/A – 1 Output Channel	Identical
Regulated Current or Regulated Voltage	Both	Both	Identical
Software/Firmware / Microprocessors Controls?	Yes	Yes	Identical
Automatic Overload Trip?	Not required because of circuit design (Current and Voltage Limited by Circuit Design and Firmware)	Not required because of circuit design Current and Voltage Limited by Circuit	Identical

Feature	New Device	Predicate Device	Comparison
		Design and Firmware	
Automatic No-Load Trip?	Yes (Reversion to Fixed Voltage Output)	Yes (Reversion to Fixed Voltage Output)	Identical
Automatic Shut off?	Yes	Yes	Identical
Patient Override Control?	Yes	Yes	Identical
Indicator Display: **a) On/Off Status?** **b) Low Battery?** **c) Voltage/Current Level?**	a) Yes, b) Yes c) Yes LED illumination on target current levels	a) Yes, b) Yes c) Yes LED illumination on target current levels	Identical
Compliance with Voluntary Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-1-11 IEC 60601-2-10 ISO 14971	IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11	Identical
Performance standard	No known required performance standards	No known required performance standards	Identical
Material/ Biocompatibility	Biocompatible materials are typically used in medical devices and are identical to predicate ZIIP+ devices.	Biocompatible materials are typically used in medical devices and are identical to predicate ZIIP devices.	Identical
Sterility	Not applicable – this device is not sold sterile	Not applicable – this device is ot sold sterile	Identical
Human Factors	Ergonomic handheld design	Ergonomic handheld design	Identical
Electrical Safety	Compliant with IEC 606011, 60601-1-2, 60601-1-11	Compliant with IEC 606011, 60601-1-2, 60601-1-11	Identical
Power Source	Internal Rechargeable Lithium Ion Battery	Internal Rechargeable Lithium Ion Battery	Identical
Charging Method	External wall adaptor	External wall adaptor	Identical
Charging Circuitry	Internal to device	Internal to device	Identical
Special Requirements	Conductive gel	Conductive gel	Identical
Wireless Capability	Bluetooth Low Energy (BLE)	Bluetooth Low Energy (BLE)	Identical

Comparison with Output Parameters with Predicate Device

Mode: Erase

S. NO.	Title	New DEVICE Myolift QT	PREDICATE DEVICE ZIIP Device (K212342)
	Output Specifications		
1.	Waveform	Symmetrical Biphasic Square wave;	Pulsed Biphasic Modulated Square Wave
2.	Shape	Square wave	Square wave
3.	Maximum Output Voltage	175 mV @500Ω 684 mV @ 2KΩ 3.20V @ 10KΩ	154mV@ 500Ω 465mV@ 2KΩ 2.2V @ 10KΩ
4.	Maximum Output Current	350µA @ 500Ω 342µA @ 2KΩ 320µA @ 10KΩ	309µA @ 500Ω 232uA @ 2KΩ 202µA @ 10KΩ
5.	Pulse Width	400000µs	Not publicly available
6.	Frequency	0.625Hz	Not publicly available
7.	Beat frequency	NA	NA
8.	For multiphasic Waveform Symmetrical Phases? Phase duration	Symmetrical	Not publicly available
9.	Net charge	Not Applicable- Battery Operated	Not Applicable- Battery Operated
10.	Maximum Phase Charge	17.5 µC @ 500Ω	6.16µC @ 500Ω
11.	Maximum Current Density	0.020 mA/cm^2 @ 500Ω	0.034 mA/cm^2 @ 500Ω
12.	Maximum Power Density	1.50 µW/cm^2 @ 500Ω	3.44 W/cm^2 @ 500Ω
13	Additional Features	Mobile Application	Mobile Application

Mode: Educate

S.No	Title	New DEVICE Myolift QT	PREDICATE DEVICE ZIIP Device (K212342)
	Output Specifications		
1.	Waveform	Symmetrical Biphasic Square wave;	Pulsed Biphasic Modulated Square Wave
2.	Shape	Square wave	Square wave
3.	Maximum Output Voltage	175 mV @500Ω 640 mV @ 2KΩ 3.2V @ 10KΩ	154mV@ 500Ω 465mV@ 2KΩ 2.2V @ 10KΩ
4.	Maximum Output Current	350mA @ 500Ω 320mA @ 2KΩ 320mA @ 10KΩ	309µA @ 500Ω 232uA @ 2KΩ 202µA @ 10KΩ
5.	Pulse Width	600000µs	Not publicly available
6.	Frequency	0.694Hz	Not publicly available
7.	Beat frequency	NA	NA
8.	For multiphasic Waveform Symmetrical Phases? Phase duration	Symmetrical	Not publicly available
9.	Net charge	Not Applicable- Battery Operated	Not Applicable- Battery Operated
10.	Maximum Phase Charge	5.25 µC @ 500Ω	6.16µC @ 500Ω
11.	Maximum Current density	0.020 mA/cm^2 @ 500Ω	0.034 mA/cm^2 @ 500Ω
12.	Maximum Power Density	1.50 µW/cm^2 @ 500Ω	3.44 W/cm^2 @ 500Ω
13	Additional Features	Mobile Application	Mobile Application

In comparison to the predicate device, there is no change or difference in the indications for use, fundamental scientific principles, performance specifications, or operation of the device. The minor differences in the construction of the devices do not raise any questions regarding the safety and effectiveness of the new device (MYOLIFT QT). The electrical values are within the limits as per the "Guidance Document for Powered Muscle Stimulator 510(k)s", issued on June 9, 1999, ANSI/AAMI NS4:2013 (R2017) standard for electrical stimulators.

The fundamental scientific technology is not changed in the new device, and the changes are solely considered for ease of use to the clinician. The Myolift QT generates the same stimulation for the face and neck for cosmetic purposes.

While designing the Myolift QT, complete care and considerable measures have been taken to retain its safety and effectiveness.

Non-clinical Testing

The following bench testing was conducted for design and performance elements deemed appropriate to demonstrate equivalence to the predicate device. The Myolift QT device met the predetermined acceptance criteria ensuring substantial equivalence to the previously cleared device. No new safety or performance issues were raised during testing.

Non-clinical Bench Testing:

- Reliability Testing
- Compliance Testing (IEC60601-1, IEC60601-1-2, IEC60601-1-11)
- Quality management systems — Requirements for regulatory purposes (ISO 13485:2016)
- Quality System Regulation (21CFR820)
- Application of usability engineering to medical devices (IEC 62366)
- Application of risk management to medical devices (ISO 14971)
- Symbols to be used with medical device labels, labelling and information to be supplied (ISO 15233)
- Biological evaluation of medical devices (ISO 10993-1)
- 47 CFR Part 15 FCC requirements of the Equipment Authorization – RF Device

CONCLUSION

The Myolift QT is substantially equivalent to the legally marketed ZIIP+ device (K212342). The Myolift QT device has similar output characteristics, principles of operation, and treatment method, and it has a identical indication for use as the predicate ZIIP+ device.

In addition, the Myolift QT device has substantially equivalent technological characteristics and principles as operation, including Bluetooth Low Energy (BLE) capability.

We believe that this pre-market submission demonstrates substantial equivalence (SE) to a legally marketed predicate device (ZIIP+ Device, K212342).