May 23, 2025

GESKE Beauty Tech GmbH
Natalia Reshetnikova
Quality Manager
Leipziger Platz 18
Berlin, 10117
Germany

Re: K250361
Trade/Device Name: SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO
Dated: February 6, 2025
Received: February 10, 2025

Dear Natalia Reshetnikova:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

Tushar Bansal -S

for Heather Dean, PhD
Assistant Director, Acute Injury Devices Team
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

Indications for Use

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K250361

Please provide the device trade name(s).

SmartAppGuided MicroCurrent Face-Lift Pen | 6 in 1

Please provide your Indications for Use below.

SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1 is intended for the stimulation of neck and facial skin and is indicated for over-the-counter cosmetic use.

Please select the types of uses (select one or both, as applicable).

- ☐ Prescription Use (Part 21 CFR 801 Subpart D)
- ☒ Over-The-Counter Use (21 CFR 801 Subpart C)

510 (k) Summary

This 510(k) Summary is being submitted in accordance with the requirements of the Safe Medical Devices Act (SMDA) of 1990 and 21 CFR 807.92 and the FDA guidance document titled "The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]" issued on July 28, 2014. All data included in this document is accurate and complete to the best of GESKE Beauty Tech GmbH knowledge.

1. Submitter

Submitter:	GESKE Beauty Tech GmbH
Address:	Leipziger Platz 18, 10117, Berlin, Germany
Phone:	+4930209674837
Email:	compliance@geske.com
Contact Person:	Natalia Reshetnikova
Date Prepared:	May 22, 2025

2. Device

Type of 510(k) Submission:	Traditional
Device Trade Name:	SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1
Device Common or Usual Name:	Face-Lift Pen
Classification Name:	Transcutaneous electrical nerve stimulator for pain relief
Regulation Number:	21 CFR 882.5890
Regulatory Class:	Class II
Product Code:	NFO

3. Predicate Devices

Name of Device:	NūFACE® Trinity
510 (k) Number:	K181008

Name of Device:	NuBODY Skin Toning Device
510 (k) Number:	K171588

Name of Device:	PureLift Pro Plus
510 (k) Number:	K221443

4. Device Description

SmartAppGuided™ MicroCurrent Face-Lift Pen| 6 in 1 is an over-the-counter stimulation device. Its enclosure is injection-molded thermoplastic resin with silicone embedded in it. The output contacts consist of an electrode composed of chrome-plated or titanium- gold plated sphere.
The device is powered by a rechargeable lithium-ion battery and cannot be used while charging. The device produces microcurrent that is discharged through two fixed, smooth spherical electrodes, and it has 3 current intensity levels that can be adjusted by pressing the on/off button on the device. Press the on/off button to turn on the device, and two spherical electrodes provide low-level electrical pulses to the target position of the face, and when the EMS function is turned on, the vibration function is also turned on simultaneously; The device spheres are designed for optimal contact with facial skin. The device delivers microcurrent as a constant biphasic square wave comprised of 10 positive pulses followed by 10 negative pulses. The microcurrent output continuously alternates between the positive and negative spherical electrodes.

5. Intended Use/Indications for Use

SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1 is intended for the stimulation of neck and facial skin and is indicated for over-the-counter cosmetic use.

6. Technological Characteristics Comparison

Comparison Tables 2A through 2D: Subject vs. Predicate Devices

Table 2A: General Information and Indication for Use Comparison Table

Elements of Comparison	Subject Device	Predicate Device (1)	Predicate Device (2)	Predicate Device (3)
Company	GESKE Beauty Tech GmbH	Carol Cole Company dba NuFACE	Carol Cole Company dba NuFACE	Xtreem Pulse LLC
Trade Name	SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1	NuFACE Trinity	NuBODY Skin Toning Device	PureLift Pro Plus
510(k) Number	K250361	K181008	K171588	K221443
Regulation Number (A1)	21 C.F.R. § 882.5890	Same as subject device	Same as subject device	Same as subject device
Regulation Name (A2)	Transcutaneous electrical nerve stimulator for pain relief	Same as subject device	Same as subject device	Same as subject device
Regulatory Class (A3)	Class II	Same as subject device	Same as subject device	Same as subject device
Product code (A4)	NFO	Same as subject device	Same as subject device	Same as subject device
Prescription or OTC (A5)	OTC	Same as subject device	Same as subject device	Same as subject device
Intended Use (A6)	SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1 is intended for the stimulation of neck and facial skin and is indicated for over-the-counter cosmetic use.	Same as subject device	NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.	Intended for facial stimulation and indicated for over-the-counter cosmetic use.
Indications for Use (A7)	SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1 is intended for the stimulation of neck and facial skin and is indicated for over-the-counter cosmetic use.	Same as subject device	NuBODY Skin Toning Device is intended for body skin stimulation and is indicated for over-the-counter cosmetic use.	Intended for facial stimulation and indicated for over-the-counter cosmetic use.
Anatomical Sites (A8)	Face and Neck	Same as subject device	Areas of the body other than the face	Face

Table 2B: Physical Characteristics Comparison Table

Elements of Comparison	Subject Device	Predicate Device (1)	Predicate Device (2)	Predicate Device (3)
Dimensions of Device (B1)	Approx. 1.14" x 0.99" x 3.9" (Model: GK series)	2.8" x 5.1" x 1.3"	2.75" x 6.5" x 6.0"	20.7cm x 4.8cm x 4.5cm
Weight (B2)	Approx. 1.3 oz.	9 oz. without charging base	Approximately 10-14 oz. without a power adapter	Unknown
Housing Materials of Main Unit (B3)	ABS & silicone	Thermoplastic	Thermoplastic	Unknown
Spheres (B4)	Stainless steel polished or with black chrome or yellow titanium gold plating	Chrome-plated	Chrome-plated	Unknown

Table 2C: Technological Characteristic Comparison Table

Elements of Comparison	Subject Device	Predicate Device (1)	Predicate Device (2)	Predicate Device (3)
Power Source (C1)	Internal rechargeable battery	Same as subject device	Same as subject device	One 3.7V Battery
Method of Line Current Isolation (C2)	Type BF	Same as subject device	Same as subject device	Same as subject device
Patient Leakage Current (C3)				
1). Normal condition	N/A – Battery operated	Same as subject device	Same as subject device	Unknown
2). Single fault condition	N/A – Battery operated	Same as subject device	Same as subject device	Unknown
External power adapter (C4)	User supplied standard 5-volt USB port	NuFACE 7-volt power adapter	NuFACE 5-volt power adapter	Unknown
Number of Output Channels (C5)	1	Same as subject device	Same as subject device	Same as subject device
Synchronous or Alternating (C6)	N/A - 1 Output Channel	Same as subject device	Same as subject device	Same as subject device
Method of Channel Isolation (C7)	N/A - 1 Output Channel	Same as subject device	Same as subject device	Same as subject device
Regulated Current or Regulated Voltage (C8)	Both	Same as subject device	Same as subject device	Regulated current
Software/Firmware (C9)	Yes	Same as subject device	Same as subject device	Same as subject device
Automatic Overload Trip (C10)	Not required due to circuit design	Same as subject device	Same as subject device	Unknown
Automatic No Load Trip (C11)	Yes	Same as subject device	Same as subject device	Unknown

Automatic Shut Off (C12)	Yes	Same as subject device	Same as subject device	Same as subject device
Patient Override Control (C13)	Yes	Same as subject device	Same as subject device	No
Indicator Display (C14)	No	Yes	Yes	Yes
On/Off Status (C15)	Yes	Same as subject device	Same as subject device	Same as subject device
Low Battery (C16)	Yes	Same as subject device	Same as subject device	Unknown
Voltage/Current Level (C17)	Yes	Same as subject device	Same as subject device	Unknown
Automatic Shut-Off (minutes) (C18)	Yes (3 min)	Yes (20 min)	Yes (5 min)	Unknown
Compliance with Voluntary Standards (C19)	IEC 60601-1 IEC 60601-1-2 IEC 60529 IEC 60601-2-10 ISO 14971 IEC 60601-1-6 IEC 62366 IEC 60601-1-11 ANSI/AMI ES60601-1 CAN/CSA-C22.2 No. 60601-1 IEC 62133	IEC 60601-1 IEC 60601-1-2	Same as subject device	ANSI/AAMI ES60601-1 IEC 60601-1-2 IEC 60601-2-10 IEC 60601-1-11
Compliance with 21 CFR 898 (C20)	Yes	Same as subject device	Same as subject device	Unknown

Table 2D: Output Characteristics Comparison Table

Elements of Comparison	Subject Device	Predicate Device (1)	Predicate Device (2)	Predicate Device (3)
Waveform (e.g., pulsed monophasic, biphasic) (D1)	Pulsed Biphasic	Same as subject device	Monophasic waveform that is delivered in a burst of pulses	Pulses Monophasic, alternating polarity
Shape (D2)	Modulated Square	Same as subject device	Same as subject device	Rectangular Pulses
Maximum Output Voltage (D3)	25.2VDC (No Load) 0.38V @500Ω 1.5 V @2kΩ 6.0V @10kΩ	28 VDC	28 VDC	20Vpp(@500Ω) 32Vpp(@2kΩ) 44Vpp(@10kΩ)
Maximum Output Current (D4)	760µA@500Ω 750 µA @2kΩ 600 µA @10kΩ	400 µA @ 500Ω Unknown (@2kΩ) Unknown (@10kΩ)	900 µA @ 500Ω Unknown (@2kΩ) Unknown (@10kΩ)	9mA(@500Ω) 4.4mA(@2kΩ) 1.2mA(@10kΩ)
Maximum Output Current Density (D5)	0.56mA/cm2 @ 500Ω	0.419 mA/cm2	0.468 mA/cm2	8.8mA/cm2 @500Ω
Output Current when not stimulating (D6)	< 1 µA	Same as subject device	Same as subject device	Unknown
Output Tolerance	+/- 10%	Same as subject	Same as subject	+/- 1mA

(D7)		device	device	
Pulse Width (D8)	60ms	Same as subject device	Same as subject device	4μs
Output Frequency (D9)	Approx. 8.3 Hz	Same as subject device	Same as subject device	1.37kHz～1.73kHz
For interferential modes, only (D10)				
a. Beat Frequency (Hz)	No Beat Frequency	Same as subject device	Same as subject device	Unknown
For multiphasic waveforms, only (D11)				
a. Symmetrical phases	Not Multiphasic	Same as subject device	Same as subject device	Same as subject device
b. Phase Duration (include units) c. (state range, if applicable) d. (both phases, if asymmetrical)	Not Multiphasic	Same as subject device	Same as subject device	Same as subject device
Net Charge (D12)	N/A - Battery operated	Same as subject device	54 μC per pulse	0μC per pulse train
Type of Energy Output (D13)	Microcurrent	Same as subject device	Same as subject device	Unknown
Pulses per burst (D14)	20	Same as subject device	Same as subject device	30
Pulses per second (D15)	8.3	Same as subject device	Same as subject device	Unknown
Burst duration (s) (D16)	2.4s	Same as subject device	Same as subject device	Unknown
Duty Cycle (D17)	50%	Same as subject device	20.2 s	Unknown
Maximum Power Density (D18)	151 μW/cm2	Unknown	4.18 mW/cm2	39600μW/cm2
Maximum Phase Charge (D19)	45.6 μC@500Ω	Unknown	1.08 mC/Burst	5.81μC@500Ω
Pulse ON time (D20)	60 msec	Same as subject device	Same as subject device	Unknown
Pulse OFF time (D21)	60 msec	Same as subject device	Same as subject device	Unknown

The following technological differences exist between the subject and predicate devices:

Dimensions of Device (B1) and Weight (B2)
Although the dimensions and net weight of the subject device differ slightly from those of the predicate device, all devices fall under the category of electrical devices designed for home use. These variations in size and weight do not affect the device's effectiveness or compromise its safety.

Housing Materials of Main Unit (B3)
The housing materials of the main unit in the subject device are different from those in the predicate device. To ensure safety, the subject device underwent comprehensive biocompatibility testing, including in vitro

cytotoxicity, skin irritation, and skin sensitization tests. The results confirmed that the device does not cause adverse skin reactions.

Spheres (B4)
The materials used for the spheres in the subject device differ from those in the predicate device. Similar to the housing materials, the subject device underwent biocompatibility testing, including in vitro cytotoxicity, skin irritation, and skin sensitization tests. The test results demonstrated that the differences in materials do not cause adverse skin reactions.

Indicator Display (C14)
The subject device does not include an indicator display, while all predicate devices have this feature. Therefore, substantial equivalence has not been met in terms of indicator display. The subject device provides tactile and sound feedback through noise and vibration. These feedback mechanisms allow the user to identify the operational status of the device effectively, compensating for the lack of a visual indicator.

Maximum Output Voltage (D3):

The subject device has a maximum output voltage of 25.2VDC (no load), which is slightly lower than the 28VDC maximum output voltage of Predicate Devices 1 and 2. The lower voltage enhances safety, and this slight decrease does not introduce any safety risks for the subject device. Medical devices designed for microcurrent applications, such as the subject device, operate at low voltage levels to ensure patient safety.

Furthermore, the subject device complies with IEC 60601-1 and IEC 60601-2-10 standards, which rigorously assess electrical safety and performance. These differences result from design variations that do not introduce new risks or affect the device's intended use. The clinical need has been achieved through a combination of increased current levels.

Maximum Output Current (D4):

The subject device delivers a maximum output current of 760 μA at a 500Ω load, which falls between the output currents of the primary predicate device (400 μA) and the secondary predicate device (900 μA). Although the secondary predicate device operates at a higher current, this difference remains within the FDA's recommended ±20% threshold for demonstrating substantial equivalence.

Furthermore, the secondary predicate device is specifically designed for skin stimulation, has been FDA-cleared for over-the-counter (OTC) home use, and is legally marketed with no known history of recalls. Given the existence of an FDA-cleared and commercially available device with higher output parameters intended for similar OTC applications, we conclude that the difference in output current between the subject device and the primary predicate device does not raise any safety concerns.

In IEC 60601-2-10, the maximum output current is specified in clause 201.12.4.104 Limitation of output parameters:
With a load resistance of 500 Ω the output current shall not exceed the limits in Table 201.101: 50mA current limit for pulse frequencies ≤ 400 Hz.
Both values (I_{peak} and I_{RMS}) of the subject device are significantly lower than the limit defined by the standard.

Furthermore, other devices cleared under the same FDA product code (NFO) exhibit even higher output currents. For instance, Predicate Device 3 demonstrates a maximum current of 9 mA at 500 Ω, substantially higher than both the subject device and the primary predicate.

Given the substantial margin between the subject device's output current and the IEC 60601-2-10 safety limit of 50 mA, the documented clearance of higher-current predicate devices by the FDA, and the presence

of Predicate Device 2 exhibiting a current difference within the FDA's recommended ±20% threshold, we conclude that the current difference between the subject device and the primary predicate device does not raise any safety concerns.

Maximum Output Current Density (D5):

The subject device exhibits a maximum output current density of 0.56 mA/cm^2 at 500 Ω, which is slightly higher than those of Predicate Device 1 (0.418 mA/cm^2) and Predicate Device 2 (0.468 mA/cm^2) but remains significantly lower than that of Predicate Device 3 (8.8 mA/cm^2). The difference in current density between the subject device and Predicate Device 2 does not exceed the ±20% threshold recommended by the FDA for substantial equivalence.

According to IEC 60601-2-10, Clause 201.4.2 and Clause 201.7.9.2.101, a current density limit of 2 mA/cm^2 is identified as a level that may require special operator attention. The subject device's output current density of 0.56 mA/cm^2 is approximately 3.57 times lower than this threshold.

Given the substantial margin between the subject device's maximum current density and the IEC 60601-2-10 safety limit of 2 mA/cm^2, the FDA clearance of predicate devices with higher current densities, and the fact that the current density of the subject device remains within the acceptable range (±20%) relative to Predicate Device 2, we conclude that the current density difference between the subject device and the primary predicate device does not present any safety concerns.

Maximum Power Density (D18):

The maximum power density of the subject device is significantly lower than that of Predicate Device 2 and 3, which exhibits a maximum power density of 4.18 mW/cm2 and 39,600 μW/cm^2 accordingly. This substantial reduction in energy output ensures that the subject device does not present an increased risk of thermal or electrical injury, nor does it introduce any new concerns related to safety.
In addition, the subject device has been demonstrated to be fully compliant with the applicable requirements of IEC 60601-1 and IEC 60601-2-10.

Maximum Phase Charge (D19):

The higher maximum phase charge of the subject device, compared to Predicate Device 3, is primarily attributable to its longer pulse width. Although the subject device delivers a greater charge per phase, this is offset by its significantly lower maximum output current. Despite the increased phase charge, the device operates well within established safety limits for stimulation.

Moreover, the subject device employs a biphasic waveform with actively balanced positive and negative phases, ensuring zero net output. This charge balancing is essential for minimizing the risk of tissue damage and long-term electrochemical effects.

In addition, both tested devices comply with the requirements of IEC 60601-1 and IEC 60601-2-10. The difference in maximum phase charge does notimpact on essential performance, effectiveness, safety, or substantial equivalence.

7. Non-Clinical Performance Testing

Safety Testing
SmartAppGuidedTM MicroCurrent Face-Lift Pen | 6 in 1 device was tested and has demonstrated compliance with applicable IEC standards concerning electrical safety and EMC.
Electrical, Mechanical, and Thermal Safety Testing were conducted according to the following standards:

- ✓ IEC 60601-1: Basic safety and essential performance (Electrical Equipment)
- ✓ IEC 60601-1-11: Basic safety and essential performance (Med Dev Home Use)
- ✓ IEC 60601-1-2: EMC - Basic safety and essential performance (Electromagnetic Disturbances)
- ✓ IEC 60601-1-6: Basic safety and essential performance (Med Dev Electrical Equipment)
- ✓ IEC 60601-2-10: Basic safety and essential performance (Med Dev Home Use – nerve and muscle stimulators)
- ✓ ISO 10993-1: Biological Evaluation of Medical Devices
- ✓ IEC 60529: Ingress Protection
- ✓ IEC 62366: Usability engineering
- ✓ ISO 14971: Risk Management

Bench Testing
Bench testing was conducted to verify that the MicroCurrent Face-Lift Pen | 6-in-1 meets established performance requirements and waveform specifications within the designed tolerances. Details are provided in the Performance Testing Section of this premarket notification.
Testing utilized production-equivalent devices to assess waveform and output energy characteristics. Additionally, a third-party accredited laboratory evaluated the device in accordance with IEC 60601-2-10, which specifies safety and performance requirements for nerve and muscle stimulators.
Results from both internal and independent testing confirm that the waveform and energy characteristics of the MicroCurrent Face-Lift Pen | 6-in-1 conform to intended specifications and demonstrate substantial equivalence to the predicate device.

Software Verification and Validation Testing
Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "Content of Premarket Submissions for Device Software Functions Guidance for Industry and Food and Drug Administration Staff", issued on June 14, 2023. The software for this device was considered as a "basic" level of concern, since a failure or latent flaw in the software could not result in injury or death to the patient or operator.

Animal Study
Animal study was not required to demonstrate the substantial equivalence to the predicate devices.

Biocompatibility
The biocompatibility evaluation for the patient contacting components of the SmartAppGuided™ MicroCurrent Face-Lift Pen | 6 in 1 was performed according to ISO 10993-1 and FDA Guidance "Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"". Tests in accordance with the following standards were conducted based on contact type and duration:

- ✓ ISO 10993-1:2018
- ✓ ISO 10993-5:2009
- ✓ ISO 10993- 10:2021
- ✓ ISO 10993-12:2021
- ✓ ISO 10993-23:2021

8. Clinical Performance Data:

Clinical testing was not required to demonstrate the substantial equivalence to the predicate devices. Non-clinical bench testing was sufficient to establish the substantial equivalence of the modifications.

9. Conclusions

The subject device, the MicroCurrent Face-Lift Pen, manufactured by Geske Beauty Tech GmbH, and the predicate devices—the NuFACE Trinity (510(k) Number: K181008), NuBODY Skin Toning Device (510(k) Number: K171588) and PureLift Pro Plus (510(k) Number: K221443)—share a similar intended use. A comprehensive comparison and assessment of the differences between the subject device and all predicate devices are detailed in Tables 2A through 2D.

Biological evaluation data, software data, electrical safety and electromagnetic compatibility (EMC) data, along with bench-top performance testing, demonstrate that the subject device is as safe and effective as the predicate devices. Based on these analyses, it is concluded that substantial equivalence between the subject and predicate devices has been established.