October 26, 2026

Foreo, Inc.
% Domljanovic Danijela
QA/RA Consultant
DD Consulting
401-4080 Living Arts Dr.
Mississauga, ON L5B4N3
Canada

Re: K261625
Trade/Device Name: FAQ™ (FAQ 401); FAQ™ (FAQ 402)
Regulation Number: 21 CFR 882.5890
Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief
Regulatory Class: Class II
Product Code: NFO, OHS
Dated: September 21, 2026
Received: September 21, 2026

Dear Domljanovic Danijela:

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.

Before making any change significantly affecting the safety or effectiveness of the device, you must submit a new premarket notification in accordance with 21 CFR 807.81. 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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (Preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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 Management System Regulation (QMSR) (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,

MARY S. KESZLER -S
2026.10.26 15:27:35 -04'00'

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

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.	K261625

Please provide the device trade name(s).

FAQ™ (FAQ 401)
FAQ™ (FAQ 402)

Please provide your Indications for Use below.

FAQ™ 401/402 is intended to use microcurrent for facial and neck stimulation, and to use LED light for the treatment of wrinkles and mild to moderate acne.

- Near-infrared light 854±5 nm and Red light 637±5 nm: Intended to improve the appearance of wrinkles.
- Blue light 465±5 nm: Intended to improve the appearance of mild to moderate acne.

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

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

510(k) Summary
K261625

Date of Summary Preparation: 18 September 2026

1. Submitter's Identifications

Submitter's Name: FOREO Inc.

Address: 1525 E Pama Lane, Las Vegas, NV, USA

ZIP Code: 89119

Contact Person: Evan Feldstein

Contact Title: General Manager

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2. Correspondent's Identifications

Correspondent's Name: DD Consulting

Address: 401-4080 Living Arts Drive, Mississauga, ON Canada

ZIP Code: L5B 4N3

Contact Person: Danijela Domljanovic

Contact Title: Regulatory Consultant

Contact E-mail Address: regulatoryna@foreo.com

Telephone: 647 928 6919

3. Name of the Device

Trade Name: FAQ
Model: FAQ 401 & 402

Regulation Number: 21 CFR 882.5890

Regulation Name: Transcutaneous Electrical Nerve Stimulator For Pain Relief

Regulatory Class: Class II

Product Code: NFO, OHS

Review Panel: Neurology

4. The Predicate & Reference Devices

Predicate Device:	K200803	Bear
Reference Device:	K241102	Luna 4 plus
Reference Device:	K240378	FAQ 201/202
Reference Device:	K232795	Led Mask Exclusive MD

5. Device Description

FAQ™ 401 & FAQ™ 402 are handheld, rechargeable, devices that feature dual microcurrent to stimulate the face and neck. They also feature near-infrared LED light therapy, red LED light therapy (intended to improve the appearance of wrinkles), and blue LED light therapy (intended to improve the appearance of mild to moderate acne).

This device features Microcurrent and LEDs on the inner surface. Users can operate the device by first selecting a therapy on the App and then pressing the universal button to power it on, start treatment, and adjust intensity with quick presses. To turn off the device, press and hold the power button for 3 seconds after completing the treatment.

Designed to fit comfortably in your hand, they are wireless, USB rechargeable, and are engineered to help target appearance of wrinkles and mild to moderate acne from the comfort of your home.

6. Indications for Use

FAQ™ 401 and FAQ™402 are intended to use microcurrent for facial and neck stimulation, and to use LED light for the treatment of wrinkles and mild to moderate acne.

- Near-infrared light 854±5nm and Red light 637±5 nm: Intended to improve the appearance of wrinkles.
- Blue light 465±5 nm: Intended to improve the appearance of mild to moderate acne.

7. Comparison with Predicate Device

Table Comparison of FAQ 401&402 and Bear (K200803), FAQ 202 (K240378), Luna 4 plus (K241102) and Led Mask Platinum Exclusive MD (K232795)

Features	Subject Device	Predicate Device 1	Reference Device 1	Predicate Device 2	Reference Device 2	Remarks
Regulatory Information						
Device Name	FAQ 401 FAQ 402	Bear	Luna 4 plus	FAQ 201 FAQ 202	Led Mask Platinum Exclusive MD	/
510(K) No.	TBD	K200803	K241102	K240378	K232795	/
Regulation Number	878.4810 882.5890	882.5890	878.4810 882.5890	878.4810	878.4810	/
Regulation name	Transcutaneous Electrical Nerve Stimulator For Pain Relief	Transcutaneous Electrical Nerve Stimulator For Pain Relief	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	Laser Surgical Instrument For Use In General And Plastic Surgery And In Dermatology	SE
Regulatory Class	II	II	II	II	II	Same
Product Code	OHS, NFO	NFO	OHS, NFO	OHS,OLP	OHS, OLP	SE
Indications for Use	FAQ™ 401/402 is intended to use microcurrent for facial and neck stimulation, and to use LED light for the treatment of wrinkles and mild to moderate acne.	The Bear devices are intended for facial and neck stimulation, and are indicated for over-the-counter cosmetic use.	Luna 4 plus is a Near-Infrared Heated Cleansing Device With Red LED/NIR light & Microcurrent Massage. **Microcurrent**: indicated for facial stimulation **RED+IR**: indicated for treat periorbital wrinkles	FAQ201&202 is intended to use LED light for the treatment of wrinkles and mild to moderate acne.	LED MASK EXCLUSIVE MD is an over the counter device that is indicated for the treatment of full face wrinkles with red light and infrared light and treat mild to moderate acne vulgaris of the face.	SE

	• Near-infrared light 854 ± 5nm and Red light 637±5 nm: Intended to improve the appearance of wrinkles. • Blue light 465±5 nm: Intended to improve the appearance of mild to moderate acne.					
Basic Device Characteristics						
Apply Parts	Face and Neck	Face and Neck	Face	Face	Face	SE
Treatment regimen	3 mins per area per day	No more than 3 minutes each time	1-4 min (adjustable)	15 mins each time	20min/day, 120day	SE
Use Environment	Home Use, over the counter	Home Use, over the counter	Home Use, over the counter	Home Use, over the counter	Home Use, over the counter	Same
Power Source(s)	3.7V/DC, 420mAh, Internal rechargeable Lithium battery	3.7V/DC, 520mAh, Internal rechargeable Lithium battery	3.7V/DC, 1000mAh, Internal rechargeable Lithium battery	3.7V/DC, 680mAh, Internal rechargeable Lithium battery	3.7V/DC, 2000mAh, Internal rechargeable Lithium battery	SE, Safety complied under IEC 62133 standard

a. Method of Channel Isolation		Type BF	Type BF	Type BF	Type BF	Type BF	Same
b. Patient Leakage Current		-	-	-	-	-	/
1) Normal condition		N/A - Battery operated	N/A - Battery operated	N/A - Battery operated	N/A - Battery operated	N/A - Battery operated	Same
2) Single fault condition		N/A - Battery operated	N/A - Battery operated	N/A - Battery operated	N/A - Battery operated	N/A - Battery operated	Same
Maximum charging time		90 mins	120 mins	120 mins	120 mins	210 mins ± 10%	SE
Electrical Power Source Frequency (Nominal)		60Hz	60 Hz	60 Hz	60 Hz	60 Hz	Same
Automatic Shut Off		Yes	Yes	Yes	Yes	Yes	Same
Software/Firmware/ control		Yes	Yes	Yes	Yes	Yes	Same
Indicator for Display	On/off	Yes	Yes	Yes	Yes	Yes	Same
	Low-battery	Yes	Yes	Yes	Yes	Yes	Same
	Current level	Yes	Yes	Yes	Yes	Yes	Same
For Micro-current Function							
Electrodes		4	2	2	N/A	N/A	Different, **Note 1**
Number of output modes		1	1	1	N/A	N/A	Same
Number of output channels		1	1	1	N/A	N/A	Same
User Microcurrent Strength selectable		5	5	Adjustment	N/A	N/A	SE
Automatic overload trip		Not required due to circuit design	Not required due to circuit design	Not required due to circuit design	N/A	N/A	Same
Automatic no-load Trip		Yes	Yes	Yes	N/A	N/A	Same
Patient override		Yes	Yes	Yes	N/A	N/A	Same

control						
Burst Mode(ie, pulse trains)	-	-	-	N/A	N/A	/
a. Pulses per burst (Pb)	32	2	2	N/A	N/A	Different, **Note 1**
b. Pulses per second(Pps)	1280	100	92	N/A	N/A	= 1/tbd*Pb Different, **Note 1**
c. Burst duration （tbd）	1.88 ms	0.68 ms	0.744 ms	N/A	N/A	Different **Note 1**
d. Duty Cycle [Line (b) x Line (c)] (on time per burst)	2.4 S	0.068 S	0.068 S	N/A	N/A	= Pps*tbd Different **Note 1**
ON time	1.88 ms	0.68 ms	0.744 ms	N/A	N/A	Different **Note 1**
OFF time	23 ms	19.92ms	20.24 ms	N/A	N/A	Different **Note 1**
Regulated Current or Regulated Voltage	Both	Both	Regulated Voltage	N/A	N/A	SE
Synchronous or Alternating	N/A-1 Output channel	N/A-1 Output channel	N/A-1 Output channel	N/A	N/A	Same
Waveform	Pulsed monophasic, alternating polarity, charge-balanced	Pulsed biphasic	Pulsed monophasic, alternating polarity, charge -balanced	N/A	N/A	SE
Waveform Shape	Modulated square	Modulated square	Modulated square	N/A	N/A	Same
Maximum Output RMS Voltage (+/- 10%) (Vrms) @500Ω	0.36V	0.2V	0.28V	N/A	N/A	Different **Note 1**
Conductive	1.12 cm^2	1.28 cm^2	0.41 cm^2	N/A	N/A	Different due to the

effective electrode area (S)						structure design but no additional safety concerns
Maximum output power density @500Ω	FAQ 401: 0.25 mW/cm2 FAQ 402:0.24mW/cm2	0.062mW/cm2	0.38 mW/cm2	N/A	N/A	= Jcd*Vrms SE; within the limitation of predicates
Maximum output RMS Current (Irms) @500Ω	FAQ 401:798μA FAQ 402:763μA	400uA	560μA	N/A	N/A	Different **Note 1**
Maximum Current Density (Jcd) @500 Ω	FAQ 401:0.71mA/cm2 FAQ 402: 0.68 mA/cm^2	0.31 mA/cm2	1.37 mA/cm2	N/A	N/A	=Irms / S Different **Note 1**
Output current when not simulating	<1μA	<1μA	<1μA	N/A	N/A	Same
Output tolerance	±10%	±10%	±10%	N/A	N/A	Same
Pulse width (specify units) （tpw）	0.038 msec	0.34 msec	0.29 msec	N/A	N/A	Different, **Note 1**
Frequency Range	40 Hz	50 Hz	46 Hz	N/A	N/A	Similarity
For interferential modes, only	-	-	-	N/A	N/A	/
a. Beat Frequency	No beat frequency	No beat frequency	No beat Frequency	N/A	N/A	Same
For multiphasic waveforms, only	-	-	-	N/A	N/A	/

a. Symmetrical phases	Not multiphasic	Not multiphasic	Not Multiphasic	N/A	N/A	Same
b. Phase duration (include units) c.(state range, if applicable) d.(both phases, if asymmetrical)	Not multiphasic	Not multiphasic	Not Multiphasic	N/A	N/A	Same
Maximum Net charge (µC per pulse) (Cn)	0 µC	0 µC	0 µC	N/A	N/A	Same
Maximum phase charge (Cb)	0.03µC@500Ω	0.14 µC@500Ω	0.16µC@ 500Ω	N/A	N/A	=Irms* tpw Different, **Note 1**
Maximum charge density	0.027µC/cm2	0.01µC/cm2	0.39µC/cm2	N/A	N/A	=Cb/S SE
For LED Light Irradiation function						
Irradiation area	10.24cm²	N/A	6.15cm²	235cm²	Not publicly available	Different **Note 2**
LED quantity	FAQ 401:8 LED FAQ 402:8 LED +4 NIR	N/A	8 LED+8 NIR	FAQ 201:50 LED FAQ 202: 50 LED+4 NIR	1026 ea	Different **Note 2**
Visible LED Wavelength	FAQ 401: Red (637nm±5nm) Blue (465±5nm) FAQ 402: Blue(465±5nm) Red (637±5nm) IR(854±5 nm)	N/A	RED: 633±10nm NIR:850±10nm	Red (637±5nm) IR(854±5 nm); Blue (465±5nm)	Blue(415 nm) RED(655 nm) NIR(845 nm)	SE
Optical Power Density(mW/cm2)	• FAQ 401: Red: 3.4 Blue: 3.2 • FAQ 402: Red+IR:8.7 Blue: 3.1	N/A	RED+IR:63	• FAQ 201: Red:20.5 Blue:12.5 • FAQ 202: Red+IR: 23 Blue: 13.9	Red+IR: 2 Blue: 1	Different **Note2**

Additional Features						
Weight	105 g/pc	91g/pc	150g/pc	169g/pc	690g/pc	Different, no impact on safety
Dimensions (mm)	143.3x 40x 42.9	64 x 79 x 39	82x38x102	162 x 100 x 182	223 x 313 x 172	Different, no impact on safety
Housing material and construction	Silicone PC+ABS stainless	Silicone PC+ABS stainless	Silicone, PC+ABS glass, gold, zinc alloy	ABS, Silicone	Not publicly available	Similarity
User interface	On/off Power button LED Color indicator Plus & Minus Buttons	On/off Power button LED Color indicator	Power button on/Off Deep cleansing mode button Regular cleansing mode button	On/off Power button LED Color switch LED Color indicator	Touch sensor LED indicator	Similarity
Environment for operating	Relative humidity : 40%-80%	Relative humidity : 15%-93%	Relative humidity : 40%-80%	Relative humidity : 15%-93%	Relative humidity : 30%-75%	Similarity
Environment for storage	-10°-50°C	-10°-50°C	-10°-50°C	-10°-50°C	-20°-50°C	Similarity
Biocompatibility	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10 ISO 10993-23	ISO 10993-5 ISO 10993-10	Similarity
Electrical Safety	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-10 IEC 60601-2-57	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	IEC 60601-1 IEC 60601-1-6 IEC 60601-1-11 IEC 60601-2-57 IEC 62471	Similarity
EMC	IEC 60601-1-2 IEC TS 60601-4-2	IEC 60601-1-2	IEC 60601-1-2	IEC 60601-1-2 IEC TS 60601-4-2	IEC 60601-1-2	Similarity
Compliance with 21 CFR 898	Yes	Yes	Yes	Yes	Yes	Same

Comparison in Details

Note 1 :

Though the electrical microcurrent stimulation characteristics of the FAQ 401&402 (including Electrodes, Burst Mode, ON/OFF time, Max output RMS, Conductive effective electrode area, Maximum phase charge, Pulse width) differ from the predicate devices, these parameters are components of a proprietary waveform design intended to produce controlled skin stimulation within the same intended treatment area; they alone do not determine delivered energy and tissue stimulation, its safety relevance was evaluated together with pulse duration, phase charge, RMS output, current density, power density, duty cycle, treatment duration.

Also, the subject device has been evaluated according to IEC60601-1 and IEC 60601-2-10 for nerve and muscle stimulators. The testing did not identify unsafe output conditions or unacceptable risk of overstimulation under the evaluated maximum output conditions.

Note 2:

Although the LED light characteristics of the wavelength the FAQ 401&402 (including Irradiation area, LED quantity) differ from the predicate devices, the LED Optical Power density in the subject device is within the scope of predicates, also the subject device has successfully passed testing in accordance with IEC 60601-2-57 and IEC 62471 standards. Therefore, these differences are not expected to pose any concerns regarding the safety or effectiveness of the device.

Clinical Tests Performed:

A clinical study was conducted to support the safety and effectiveness of the FAQ 401 and FAQ 402 devices but not evaluated for substantial equivalence.

Biocompatibility Testing

The subject device has been tested in compliance with the following standards and no additional risks concerning safety and effectiveness were noted;

- ISO 10993-5, Biological Evaluation of Medical Devices - Part 5: Tests for InVitro Cytotoxicity
- ISO 10993-10, Biological Evaluation of Medical Devices - Part 10: Tests for Irritation and Skin Sensitization.
- ISO 10993-23 Biological evaluation of medical devices Part 23: Tests for irritation

Electrical Safety and Electromagnetic Compatibility Testing

Category	Standards	Standards Desc
Safety	IEC 60601-1:2005/AMD1:2012/AMD2:2020	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
	CAN/CSA-C22.2 NO. 60601-1:14	
	AAMI 60601-1:2005 + AMD 1:2012	
	IEC 60601-1-6:2010+ AMD1:2013 +AMD2:2020	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
	IEC 62366-1:2015+ AMD1:2020	Medical devices - Part 1: Application of usability engineering to medical devices
	IEC 60601-1-11:2015+AMD1:2020	Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral Standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
	EN 60601-2-10:2015+A1:2016	Medical electrical equipment - Part 2-10: Particular requirements for the basic safety and essential performance of nerve and muscle stimulators
	IEC 60601-2-57: 2011	Medical electrical equipment - Part 2-57: Particular requirements for the basic safety and essential performance of non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
EMC	EN 60601-1-2: 2015+A1:2021 IEC 60601-1-2: 2014 +A1:2020	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
	IEC TS 60601-4-2:2024	Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems

Software Verification and Validation

Software documentation consistent with Minor level of concern was submitted in this 510(k) per the FDA guidance document, “Content of Premarket Submissions for Device Software Functions” issued

on June 14, 2023. System validation testing presented in this 510(k) demonstrated that all software requirement specifications are met and all software hazards have been mitigated to acceptable risk levels.

Cybersecurity

The cybersecurity risks associated with the FAQ™ 401&402 were evaluated as follows:

- Identification of assets, threats, and vulnerabilities;
- Assessment of impact of threats and vulnerabilities on device functionality and end user;
- Assessment of the likelihood of threats and of a vulnerability being exploited;
- Determination of risk levels and suitable mitigation strategies;
- Assessment of residual risk and risk acceptance criteria

The cybersecurity risk analysis performed, the controls identified, the comparison with the National Vulnerability Database, and the labeling information detailed with the Cybersecurity Assessment demonstrated that all risks associated with network capable interfaces of the device have been adequately mitigated.

8. Conclusion:

Based on comparison of intended use and technical characteristics, the subject device FAQ401 & FAQ402 is similar to the legally marketed predicate Bear & FAQ 202 and Luna 4 plus. Hardware and software verification and validation demonstrated the FAQ401 & FAQ402 met all performance specifications.

Any differences between the FAQ401 & FAQ402 and the predicate devices do not raise new types of questions of safety and effectiveness. Therefore, the FAQ 401 & FAQ402 is substantially equivalent to the predicate devices.