April 9, 2020

Refine USA LLC
% Wayne Glover
President
TechniReg, Inc
19404 Pine Valley Drive
Odessa, Florida 33556-3955

Re: K192138
Trade/Device Name: Rejuvapen NXT
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling device for aesthetic use
Regulatory Class: Class II
Product Code: QAI
Dated: February 28, 2020
Received: March 6, 2020

Dear Wayne Glover:

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,

Kimberly M. Ferlin, Ph.D.
Assistant Director (Acting)
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192138

Device Name
Rejuvapen NXT

Indications for Use *(Describe)*

The Rejuvapen NXT is a microneedling device and accessories intended to be used as a treatment to improve the appearance of periorbital wrinkles in Fitzpatrick skin types I-IV. The Rejuvapen NXT is intended for use on adults at least 22 years of age.

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

This 510(k) Summary of safety and effectiveness is being submitted in accordance with the requirements of 21 CFR 807.92.

Summary Date: April 8, 2020

Manufacturer: Refine USA LLC

Telephone: 866-590-5533

Establishment Registration No.: 3006033709

Contact Person: Mr. Brian Smith
President
Phone: (904) 629-0100
Fax: (888) 842-0395

Trade Name: Rejuvapen™ NXT

Common Name: Powered Microneedle Device

Classification Name: Microneedling device for aesthetic use (21 CFR 878.4430)

Product Code: QAI

Equivalence / Predicate Device: Substantial equivalence to the following legally marketed predicate devices is claimed:

Device Name:	510(k) No.:	Date:
SkinPen® Precision System	DEN160029	03/01/2018

Description: The Rejuvapen is a handheld instrument that contains a Single Use micro needle cartridge containing 12 stainless steel microneedles in a circular arrangement with an adjustable microneedle depth of up to 2.5 mm. The needles create very small punctures in the epidermal and dermal layers of the skin. The device is powered by a medical grade wall plug-in supply. An adjustment is provided for a variable speed motor that controls the frequency of the puncture process with a total of 9 user selectable steps.

Geometry consists of 12 microneedles in a circular arrangement with rows of 2-4-4-2.

The Rejuvapen may be used with the operator and/or patient in any position that is comfortable. There are no restrictions for other nearby persons.

Caution: Federal law restricts this device to sale by or on the order of a physician. This is a Class II device (USA).

Intended Use: The Rejuvapen NXT is a microneedling device and accessories intended to be used as a treatment to improve the appearance of periorbital wrinkles in Fitzpatrick skin types I-IV. The Rejuvapen NXT is intended for use on adults at least 22 years of age.

Predicate Device: The Rejuvapen NXT characteristics with its included accessories and intended use are compared to the following predicate device:

- SkinPen® Precision System (DEN160029) manufactured by Bellus Medical, LLC.

Please refer to data in the comparison chart for comparison of the design, materials, chemical composition, packaging, intended use, mechanical performance and other characteristics of the subject device to those of the predicate devices.

Biocompatibility: The biocompatibility endpoints were evaluated to the following standards:

- Cytotoxicity – ISO 10993-5
- Skin irritation – ISO 10993-10
- Skin sensitization – ISO 10993-10
- Pyrogenicity – USP <151>
- Acute Systemic Toxicity – ISO 10993-11

EMC: Electromagnetic Compatibility testing was performed on the device and its power supply adapter by an NRTL and complies with IEC 60601-1-2 Medical Electrical Equipment, Electromagnetic Compatibility.

Essential Performance:

The Rejuvapen NXT has been tested for electromagnetic immunity and emissions. The basic safety and essential performance of the device is maintained if the user follows the rules, distances and exclusions described in the information and tables that follow.

The essential performance of Rejuvapen NXT microneedling device is defined as;
a) Needle protrusion: Maximum needle protrusion is a needle protrusion setting of 2.5 + 0.25 mm.

Note: As the dial for the needle protrusion setting is mechanical, this needle protrusion cannot be influenced by EMC, electronic or electric phenomena.
b) Puncture frequency: Maximum puncture frequency of 110 Hz + 2 %

Electrical Safety: Electrical Safety testing was performed on the device and its power adapter by an NRTL and fulfil the requirements of ANSI AAMI ES60601-1:2005/(R)2012 + A1:2012 + C1:2009(R)2012 + A2:2010(R)2012 (Consolidated Text) Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance (IEC 60601-1:2005, MOD).

Shelf Life and Sterilization Validation: The shelf life of the handheld unit and microneedle cartridge is 2 years and was verified by testing in accordance with the shelf life and sterilization validation test report. References include ISO 11607 and FDA guidance document 'Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile', March 2016.

Technical Specifications:
Needle Length: 3.0mm - includes length inside molded housing
Geometry: 12 needles in a circular arrangement outer circle of 8, inner circle of 4
Maximum Penetration Depth Setting: 2.5mm
It is not recommended to use the device at depths greater than 1.3mm
Puncture Rate Frequency: User adjustable in 9 steps from 80 to 110 Hz
(4800 to 6600 RPM)
Needle Penetration Depth Accuracy: ±0.25mm.
Puncture Rate Accuracy: ±2%

General controls and mitigation measures

To support substantial equivalence of the Rejuvapen NXT Microneedling device system, it has undergone non-clinical performance tests in line with recognized standards in terms of general requirements, biocompatibility, electrical safety and software.

The following non-clinical performance data is provided in support of the substantial equivalence determination

Summary of Risk and mitigation measures

Identified Risk to Health	Mitigation Measures	Substantiation
Safety profile	Biocompatibility evaluation	ISO 10993-5, ISO 10993-7, ISO 10993-10, ISO 10993-11, USP 40 part 151, and ISO 10993-12
	Labeling	ISO 15223-1:2012, EN 1041:2008, IEC 82079-1:2012, IEC 62366:2007
Cross contamination and infection	Sterilization validation	ISO11135-1:2007 ISO/TS11135-2:2008 ISO11737-1:2006
	Reprocessing validation	A cleaning validation and a low-level disinfection validation was performed (Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling). In addition, the use of a protective sleeve is required.
	Non-clinical performance testing	Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The following performance characteristics were tested: i. Accuracy of needle penetration depth and puncture rate in pig skin ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection due to a safety membrane; and iii. Identification of the maximum needle penetration depth for the device in pig skin
	Shelf life testing	Performance data supports the shelf life of the device by demonstrating continued sterility, package integrity, and device functionality over the intended shelf life according to ISO 11607-1, ISO11607-2 and ISO 11737-2
	Labeling	ISO 15223-1 EN 1041 IEC 82079-1 IEC62366
Identified Risk to Health	**Mitigation Measures**	**Substantiation**

Electrical shock or Electromagnetic interference with other devices	EMC testing and electrical safety testing	IEC / ES60601-1 IEC60601-1-2 IEC60601-1-6
	Labeling	ISO 15223-1 EN 1041 IEC 82079-1 IEC62366
Exceeding safe penetration depth Mechanical failure Software malfunction	Non-clinical performance testing	Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The following performance characteristics were tested: i. Accuracy of needle penetration depth and puncture rate in pig skin ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection due to a safety membrane; and iii. Identification of the maximum safe needle penetration depth for the device in pig skin
	Technological characteristics	Non-clinical performance data demonstrates that the device performs as intended under anticipated conditions of use. The manufacturer has set tolerances for maximum needle depth penetration and puncture rate and has performed bench testing to demonstrate the efficacy of fluid ingress protection. The following performance characteristics are tested: i. Accuracy of needle penetration depth, maximum needle depth penetration and puncture rate was tested in a clinically suitable substrate porcine skin. Two penetration depths of 0.5mm and 2.5mm were tested at frequencies (puncture rate) of 80 and 110Hz using aged cartridges and aged devices to verify the accuracy of the penetration depth, maximum permissible depth and puncture rate. A tolerance was set of ± 0.25mm for needle penetration and a 2% tolerance of puncture rate. In all tests and in all variations the accuracy of needle penetration depth and puncture rate were within the expected tolerances. The maximum needle depth penetration of the device in worst case scenario did not

		exceed the tolerances set by the manufacturer. ii. Safety features built into the device to protect against cross-contamination, including fluid ingress protection. The micro needling cartridge contains a safety membrane (seal) that was tested under laboratory conditions. Testing of the seal under a worst-case scenario (maximum puncture rate and needle penetration depth) did not result in the penetration of viral particles, protein or hemoglobin markers through the seal to the chamber of the device. iii. Identification of the maximum needle penetration depth for the device in pig skin.
	Shelf life testing	ISO 11607-1 ISO 11607-2
	Labeling	ISO 15223-1 EN 1041
	Software verification, validation and hazard analysis	IEC 62304

Technological Characteristics

Property:	Rejuvapen NXT	SkinPen® Precision System	Significant differences
Device Manufacturer	Refine USA, LLC 340 3rd Avenue South Suite C Jacksonville Beach, FL 32250	Bellus Medical, LLC 4505 Excel Parkway Suite 100 Addison, TX 75001	Not Applicable
Device Tradename	Rejuvapen NXT	SkinPen® Precision System	Not Applicable
510(k) Number	K192138	DEN160029	Not Applicable
Device Classification Name	Microneedling device for aesthetic use	Microneedling device for aesthetic use	Identical
Device Product Code	QAI	QAI	Identical
Device Classification	Class II	Class II	Identical
Regulation Number	21CFR 878.4430	21CFR 878.4430	Identical
Use	Prescription Only	Prescription Only	Identical
Intended Location of Use	Face	Face	Identical
Indications for Use and Intended Use	The Rejuvapen NXT is a microneedling device and accessories intended to be used as a treatment to improve the appearance of periorbital wrinkles in Fitzpatrick skin types I-IV. The Rejuvapen NXT is intended for use on adults at least 22 years of age.	SkinPen® Precision System is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older	Dissimilar - clinical data was provided to support the indication
Geometry	12 needles in a circular arrangement: outer circle of 8, inner circle of 4	14 needles in a circular arrangement: outer circle of 7, inner circle of 6, middle has 1	Dissimilar - Non clinical performance testing using pig skin demonstrates that the needle geometry of the proposed device is uniform and does not raise any different questions in relation to safety, compared to the predicate device.

Property:	Rejuvapen NXT	SkinPen® Precision System	Significant differences
Needle protrusion settings	0 – 2.5mm	0 – 2.5mm	Identical
Max. Penetration Depth	2.5mm	2.5mm	Identical
Puncture Rate Frequency	80Hz to 110Hz user adjustable, 9 regulated speeds	105Hz to 136Hz unregulated	Dissimilar – Proposed device does not exceed the frequency of the predicate device. Bench testing was provided to support the difference in technology.
Treatment Protocol	4 treatments spaced 4 weeks apart	3 treatments spaced 4 weeks apart	Identical

Substantial Equivalency and Comparison of Technological Similarities and Differences:

Key Similarities:

1. The device classification (generic description) and basic technologies are equivalent in that both devices are micro needling devices containing more than 1 needle that mechanically punctures and injures the skin for aesthetic use.
2. Both devices are by prescription use only.
3. Both use a circular arrangement for the micro-needles.
4. Both have a maximum penetration depth of 2.5mm.
5. Both use treatment tips that are disposable and for single use only.

Differences:

Although the devices share the basic generic description and technologies they do differ in several areas.

a. Indication
b. Geometry and needle count
c. Puncture rate frequency

These differences have been addressed by the manufacturer through the applicable safety standards, general controls, non-clinical, and clinical testing.

Clinical performance testing

A clinical study was conducted to support the safe and effective use of the Rejuvapen NXT Microneedling device for the treatment of Periorbital wrinkles.

The study was conducted at a single center. 52 healthy volunteers with facial ageing were recruited. After informed consent, subjects underwent 4 micro needling sessions 4 weeks apart. Subjects were assessed at baseline and 30 days after the last treatment, on Day 120.

The subject's face was cleansed with cleanser to remove all traces of make-up. A topical anesthetic (Numbmaster; 5% Lidocaine) was applied to the periorbital region for 30 minutes, as per the manufacturer's instructions. After 30 minutes the topical anesthetic was removed.

A standard microneedle cartridge containing 12 stainless steel microneedles (maximum 2.5 mm length, 32 gauge) was used to achieve pinpoint bleeding over the periorbital treatment area. The operator was instructed to start at a needle protrusion setting of 0.5 mm and gradually increase the depth until pinpoint bleeding was observed, with a maximum depth of 1.3 mm. After treatment the skin was cleansed with warm water and sterile gauze. A physical sunblock cream with SPF 40 was applied to the subject's skin.

Forty-six subjects (88%) completed all treatment visits and attended follow up. One subject was withdrawn as they had commenced Apixiban, an anticoagulant, two withdrew for no reason and did not return the research staff calls, one withdrew to undergo additional aesthetic treatments, one withdrew for personal reasons and one subject withdrew because they 'did not like the treatments'.

The mean age of the subject was 57 years (range 37-72 years). Six males, 46 females. Fitzpatrick phototypes (FP) ranged from 1-4. Six of the subjects identified as Hispanic the remainder were white Caucasian. Five of the subjects were smokers (see table 1).

Table 1 Subject demographics at baseline

N	Mean age	Age range	M:F	Hispanic	FP I	FP II	FP III	FP IV	FP V	FP VI
52	57	37-72	6:46	6	3	20	22	7	-	-

MEASUREMENT OF SAFETY

Physician measurement of safety

Immediately after each micro needling procedure the research staff graded the amount of visible erythema in the treatment area. Grading was carried out using a 5-point grading scale; whereby none was equivalent to "No erythema or redness. Skin is normal color" to Severe; "Bright or dark red color to the skin. Skin is severely red."

Subjects measurement of safety

Subjects also graded erythema, pain and discomfort experienced during the treatment. A descriptive grading scale was used for subjects to evaluate their erythema with the addition of photography. This scale was also used for subjects to record their erythema at home. Pain and discomfort were recorded using a visual analogue scale (0-10) where 0 was equivalent to "no pain" or "no discomfort" to 10, "most intense pain ever" and "most discomfort ever". This grading structure was also used to record changes to pain and discomfort at home. In addition, skin peeling was assessed by the subject from day 3 to day 8 using a visual analogue scale.

From commencement of the study to study close out adverse events were recorded and monitored by the research staff.

MEASUREMENT OF EFFECTIVENESS

Physician measurement of effectiveness

At each visit digital photographs (VISIA) were taken of the subject's face. At the end of the study the digital images of the subject's face were masked and randomized and analyzed independently by 2

physicians using the Lemperle grading scale (periorbital region). *Lemperle G, Holmes RE, Lemperle SS. A Classification of Facial Wrinkles. Plastic and reconstructive surgery. 2001 Nov 1;108(6):1735-50.

Subject measurement of effectiveness

Subjects were asked to grade their skin at baseline in respect to periorbital lines and wrinkles, and pigmentation. Thirty days after the last treatment, subjects were asked to grade their treatment response.

RESULTS

Physician Measurements of safety

There were 20 adverse events during the study, that occurred in 12/52 subjects (23%) The adverse events were judged to be mild by the principle investigator.

Fourteen (14/20, 70%) of the 20 AEs were reports of bruising in the treatment area lasting between 1-7 days. Only one event (1/20, 5%) reported bruising under both eyes and the remainder were singular occurrences, either left or right eye areas. Swelling in the treatment area was reported in two (2/20, 10%) of subjects and blotchy skin and bruising were reported in one subject (1/20(5%)). One subject (1/20(5%)) reported 'watery eyes' and a post-treatment allergic response after three treatment visits. There were no unrelated adverse events.

All the incidents were self-limiting and required no intervention from study staff.

Erythema immediately after treatment was graded by the physician as predominantly minor or mild (see table 2) in subjects (with the remainder of subjects graded as moderate. No subjects were graded as severe.

Table 2 Physician Erythema grading - Immediately post treatment

Physician Erythema grading - Immediately post treatment						
	None	**Minor**	**Mild**	**Moderate**	**Severe**	**Number of subjects**
Treatment 1	0	25 (48%)	22 (42%)	5 (10%)	0	52
Treatment 2	0	30 (61%)	17 (35%)	2 (4%)	0	49
Treatment 3	0	29 (63%)	15 (33%)	2 (4%)	0	46
Treatment 4	0	32 (70%)	13 (28%)	1 (2%)	0	46

Subject evaluation of pain and discomfort during treatment indicated a mean pain score of 2.1 over the four treatments (based on a 0-10 scale) with a range from 0-7, and a mean discomfort score of <1, with a range from 0-7 (based on a 0-10 scale).

Subject measurement of safety

Immediately after treatment, 12/46 (26%) of subjects recorded their erythema as severe ('bright or dark red color to the skin; skin is severely red') 24/46 (52%) of subjects recorded their erythema as moderate ('skin has a very definite redness to it'), and 10/46 (22%) recorded their erythema as mild or minor.

One day after the treatment the number of subjects recording their erythema as severe was 5/46 (11%). By the evening of Day 3 the number of subjects reporting their erythema to be mild, minor or absent was 44/46 (96% of subjects). By Day 8 only one subject 1/46 (2%) graded their erythema as mild, the remainder recording erythema as either minor (2/46; 4%) or none (44/46; 96%).

Subjects reported gradual cessation of pain after the treatment. By the evening of Day 2 (on a scale of 0 to 10) the mean pain score was 0.5 and by Day 4 the mean pain score was zero.

Subjects reported gradual cessation of discomfort over the days after the procedure, with a mean discomfort score of <1 (on a scale of 0 to 10) recorded on the evening of Day 2.

Physician measurement of effectiveness

A statistical summary of the evaluation of periorbital wrinkle grading is given in Table 3, showing mean values, numbers/percentages of improvements and 95% confidence intervals (CIs).

Two blinded evaluators graded images at baseline and final follow up (Day 120).

For the 37 subjects for whom the two physicians gave the same grade improvement the mean improvement was 0.57. Nineteen out of 45 subjects, 42% had at least a one grade improvement according to both assessors

Table 3: Combined Assessment of periorbital wrinkles at baseline and Day 120 (95% CIs in brackets)

Physician	n	Mean baseline grade	Mean Day-120 grade	Mean improvement	Number; % of subjects improved by ≥ 1 grade
Combined	37	2.68	2.11	0.57 (0.37, 0.76)	19; 42% (35.2%, 67.5%)

[3] Mean baseline grade = 2.67 for all 52 recruited subjects.

Subject measurement of effectiveness

On average, subjects graded their skin at baseline as slight/shallow lines and wrinkles that are noticeably visible, isolated regions of skin roughness and slight pigmentation and sunspots. Thirty days after the last treatment 37/46 (80%) of subjects graded their treatment responses as “slight to somewhat noticeable improvement in periorbital wrinkles” and 23/46 (50%) “slight improvement in pigmentation”

Five of the 46 subjects (5/46(11%)) reported no improvement in any of the efficacy parameters.

Conclusions: The Rejuvapen NXT is substantially equivalent to the predicate device. There are no different questions regarding safety or effectiveness.