October 21, 2022

℅ Laurie Clarke
Executive Vice President & Principal
Technology Sciences Group, Inc.
1150 18th Street NW, Suite 475
Washington, District of Columbia 20036

Re: K222199
Trade/Device Name: Collagen P.I.N. (Percutaneous Induction Needling)
Regulation Number: 21 CFR 878.4430
Regulation Name: Microneedling Device For Aesthetic Use
Regulatory Class: Class II
Product Code: QAI
Dated: July 22, 2022
Received: July 22, 2022

Dear Laurie Clarke:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K222199

Device Name
Collagen P.I.N. (Percutaneous Induction Microneedling) System

Indications for Use *(Describe)*
The Collagen P.I.N. (Percutaneous Induction Needling) microneedling system is indicated for use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, aged 22 years and older.

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

Induction Therapies LLC
Collagen P.I.N. (Percutaneous Induction Needling) System (K222199)

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Induction Therapies LLC
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Contact Tel: (502) 594-3116

Contact Person: Amelia Aslam, J.D.

Date Prepared: October 19, 2022

Submission Correspondent

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Name of Device and Name/Address of Sponsor

Collagen P.I.N. (Percutaneous Induction Needling) System

Induction Therapies LLC
1920 Stanley Gault Parkway, Suite 100
Louisville, Kentucky 40223

Proprietary Name - Collagen P.I.N. (Percutaneous Induction Needling) System

Common Name - Powered Microneedle Device

Classification Regulation Number - 21 C.F.R. 878.4430

Product Code - QAI

Predicate Device
Crown Aesthetics' SkinPen Precision System (K220506)

Collagen P.I.N's Intended Use

The Collagen P.I.N. (Percutaneous Induction Needling) microneedling system is intended to be used to create microinjuries in the skin for aesthetic purposes.

Comparison of Collagen P.I.N. and its Predicate Device's Intended Use

Collagen P.I.N and SkinPen are intended to be used to create microinjuries in the skin for aesthetic purposes. Thus, Collagen P.I.N. has the same intended use as its predicate device.

Collagen P.I.N.'s Indications for Use

The Collagen P.I.N. (Percutaneous Induction Needling) microneedling system is indicated for use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, aged 22 years and older.

Comparison of Collagen P.I.N. and its Predicate Device's Indications for Use

Collagen P.I.N.'s indication for use is identical to SkinPen's second indication for use as both of these devices are indicated as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I – III, aged 22 years or older.

Collagen P.I.N.'s Technological Characteristics

The Collagen P.I.N. consists of a handheld device that creates microinjuries into the skin, by virtue of a 1A DC motor that rapidly reciprocates (7000 - 9000 rpm) an array of 35 gauge (SWG) stainless steel microneedles. The device handpiece motor body is comprised of aluminum alloy, with a dial mechanism that controls the depth of penetration of the microneedle array from 0.0 mm to a maximum of 3.0 mm.

The Collagen P.I.N. disposable needle cartridge is designed in a single configuration – a 36-pin array in a radial arrangement. The needles, which are 3.0 mm long, are composed of medical grade stainless steel, with a 1.0 mm conical taper to needle tip. The needle array is housed in a cartridge housing that prevents liquids from entering the handpiece motor body via the inside lumen of the cartridge. The needle cartridge is composed of a polycarbonate outer shell and piston, which houses the microneedle array. The microneedle array is attached to the polycarbonate shell using a silicone boot, which acts as spring mechanism which facilitates the microneedling mode of action. Each lot of disposable microneedle cartridges are individually packaged and sterilized by ethylene oxide gas ("EtO").

The device contains a rechargeable lithium-ion battery. The device is to be operated only cordlessly, and not used while the device is plugged into the wall charging station.

Comparison to the Predicate Device's Technological Characteristics

Collagen P.I.N. and SkinPen also have very similar technological characteristics in that both of these devices include a single-use cartridge containing needles that is inserted into the distal end of a reusable handpiece to which a battery pack containing a rechargeable lithium-ion battery is

attached at the proximal end of the handpiece. The primary technological differences between Collagen P.I.N. and its predicate are: (1) Collagen P.I.N.'s maximum treatment depth of 3.0 mm is 0.5 mm deeper than its predicate's maximum treatment depth of 2.5 mm; (2) its maximum puncture rate of 1915 punctures per second is 6.2% more than its predicate's maximum puncture rate of 1797 punctures per second[5]; and (3) its maximum motor speed of 9,000 RPM is 14% faster than its predicate's maximum motor speed of 7,700 RPM. However, Collagen P.I.N. does not raise any different questions of safety and effectiveness compared to its predicate as these devices present the same risks, including whether the needles will injure blood vessels and nerves below the skin surface and whether the number and pattern of needle pricks it creates cause sufficient injury to the skin tissue to have the intended therapeutic effect of improving the appearance of facial acne scars in adults with Fitzpatrick Skin Types I – III, aged 22 years or older.

Performance Data - Non-Clinical

Biocompatibility

Collagen P.I.N. is an external communicating, indirect blood path device – with "limited" contact of < 24 hours. As such, Collagen P.I.N. requires Cytotoxicity, Irritation & Intracutaneous Reactivity, Skin Sensitization, Acute Systemic Toxicity, and Material-Mediated Pyrogenicity testing per Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1". The following table summarizes biocompatibility testing conducted on Collagen P.I.N. Those tests demonstrate the biocompatibility of Collagen P.I.N for use as "a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Type I - III, aged 22 years and older.

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Biocompatibility Test / Standard	Success Criteria	Test Result	Conclusion
In Vitro Cytotoxicity ISO 10993-5 Third Edition, 2009-06-01	**Qualitative Evaluation** Numerical Grading Scale: 0 to 2 Grade < 2, non-cytotoxic **Quantitative Evaluation** Extract viability validation >70% viability, non-cytotoxic	**Qualitative Evaluation** No change in the morphology (Grade 0) was observed. **Quantitative Evaluation** Viability ranged from 91.30% - 97.95%.	**PASS**
Intracutaneous Reactivity ISO 10993-10 Third Edition, 2010-08-01	**Qualitative Evaluation** Numerical Grading Scale: 0 to 4, - Both Erythema & Oedema Formation Maximum Possible Score = 8	**Avg Graded Score = 0** No mortality or morbidity were observed. All animals showed an increase in body weight The difference of the mean skin reaction scores for the test item extracts and the vehicle control was zero.	**PASS**
Skin Sensitization ISO 10993-10 Third Edition, 2010-08-01	**Acceptance Criteria** 1. Positive control trial conducted within the test facility should give clear positive results. 2. No response should be observed in negative control treated animals	No mortality or morbidity were observed. All animals showed an increase in body weight. No gross and histopathological examination were found necessary. No evidence of sensitization was seen in any of the test item extracts treated animals	**PASS**
Acute System Toxicity ISO 10993-11 Third Edition, 2017-09	**Acceptance Criteria** 1. None of the animals treated with test item should show a significantly greater biological reactivity than animals treated with solvent control. 2. None of the animals in the control group should show significant loss of body weight. 3. No mortality or abnormal behavior such as convulsions or prostration should occur in control group animals.	Control animals showed no biological reactions All animals showed an increase in body weight No signs of ill health or overt toxicity No animals were found dead or in moribund condition	**PASS**
Material Mediated Pyrogenicity ISO 10993-11 Third Edition, 2017-09	**Acceptance Criteria** 1. The control temperature should not vary by more than 1°C. 2. The test animal's temperature should be less than 39.8 °C. 3. None of the treated animals should show an individual body temperature increase of 0.5°C or more compared to its control temperature.	The variation in control temperatures between the 3 animals was less than 1 °C. The control temperatures in 3 animals did not exceed 39.8 °C (38.4, 38.7, and 38.2 °C) The animals didn't show any individual temperature increases of 0.5 °C or more when compared to its control temperature.	**PASS**

Cleaning/Disinfection Method Validation

The only component of Collagen P.I.N. that is reusable is the device's handpiece. The Collagen P.I.N's User Guide contains the following instructions for cleaning/disinfecting its handpieces after each use: remove all visible debris from the surface of the handpiece prior to intermediate level disinfection. Validation testing was conducted on handpieces cleaned and disinfected in accordance with those instructions the handpiece met the sponsor's performance criteria for a 3-$\log_{10}$ (99.9%) reduction of each microorganism bioload reduction for the following microorganisms; *Staphylococcus aureus (S. aureus)*, *Pseudomonas aeruginosa (P. Aeruginosa*), *Escherichia coli (E. coli*), *Klebsiella pneumoniae (K. pneumonia*), and *Mycolicibacter terrae (M. terrae*) - in a nine (9) minute contact time. Disinfection Method Validation of the Collagen P.I.N. handpiece achieved the microbial load reduction performance criteria for each microorganism.

Validation of ETO Sterilization

Collagen P.I.N.'s 36-pin microneedle cartridge is supplied sterile. They are sterilized using an ethylene oxide sterilization cycle of 90% EtO and 10% CO_2 to achieve a sterility assurance level of 10^{-6}, which equates to a 99.9999% reduction of targeted microorganism populations. This EtO sterilization was designed and validated per ISO 11135:2014 "*Sterilization of health care products – Ethylene oxide – Requirements for development, validation and routine control of a sterilization process for medical devices*", which is an FDA-recognized consensus standard.

The validation testing showed that this method of sterilizing Collagen P.I.N.'s 36-needle cartridge achieved a 6-$\log_{10}$ reduction. In addition, ethylene oxide ("EtO") residuals were not detectable on the needle cartridges and thus, they were below the specified limit of 0.5µ. per lens. Their ethylene chlorohydrin ("ECH") residuals were also not detectable and thus below the specified limit of 2µ per lens. Accordingly, the results of this test validated this method of sterilizing the 36-pin microneedle cartridges.

Shelf Life Testing Validation

Induction Therapies tested the sterile microneedle cartridges for conformance to the following standards to evaluate the impact of storage on their sterility and performance.

- Accelerated Aging per ISO 11607-1 + AMD 1:2014 "Packaging for terminally sterilized medical devices – Part 1: Requirements for materials, sterile barrier and packaging systems" ASTM F 1980:2016, which equated to 2 years, real-time aging;
- Visual Inspection per ASTM 1886:2016 "Standard Test Method for Determining Integrity of Seal for Flexible Packaging by Visual Inspection",
- Internal Pressure (Bubble test) per ASTM F2096:2011 "Standard Test Method for Detecting Gross Leaks in Packaging Pressurization (Bubble Test)";
- Seal Strength per ASTM F 88A:2015 – Technique A and EN 868-5:2009 – Annex D; and
- Integrity - Dye Penetration ASTM F 1929:2025 – Technique A "Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

Testing was conducted on 1,000 aged samples, 900 of which are the 36-needle cartridge subject to this clearance. Accelerated aging for 46 days was used to simulate storage for one year and for 91 days to simulate storage for two years. The aged samples passed the visual inspection internal pressure (bubble test), the seal strength test, and the integrity – dye penetration test at both time points. Thus, the testing validates the microneedle cartridges labeled two-year shelf life.

Transport Simulation **Testing**

Validation testing on 900 units of the 36-needle cartridge for which Induction Therapies is seeking clearance in this submission, as well as 100 units of the 12-needle version of that cartridge, which the Company no longer intends to market in the U.S. The accelerated aging was calculated for 91 days for the 2-year shelf-life validation test and 46 days for the one-year shelf-life validation test. The needle cartridge passed the visual inspection internal pressure (bubble test), the seal strength test, and the integrity – dye penetration test for both the 2-year validation and the 1-year validation testing. Thus, the testing demonstrated the needle cartridge's 2-year shelf life. The 2-year shelf-life validation test report is provided in Attachment 14B-1. The one-year shelf-life validation test report, which constitutes interim results, is provided in Attachment 14B-2.

Transport Simulation testing per ISTA 2A on Collagen P.I.N.'s needle cartridges was also conducted. The testing was conducted on 900 units of the 36-needle cartridge for which Induction Therapies is seeking clearance in this submission, as well as 100 units of the 12-needle version of that cartridge, which the Company no longer intends to market in the U.S. More specifically, the following testing was conducted:

- Transport simulation ISTA 2A;
- Visual Inspection per ASTM 1886:2016 Standard Test Method for Determining Integrity of Seal for Flexible Packaging by Visual Inspection;
- Internal Pressure (Bubble test) per ASTM F2096:2011 Standard Test Method for Detecting Gross Leaks in Packaging Pressurization (Bubble Test);
- Seal Strength per ASTM F 88A:2015 â€“ Technique A and EN 868-5:2009 Annex D; and
- Integrity - Dye Penetration ASTM F 1929:2025 â€“ Technique A Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration.

No visible changes were observed for the conditioning and vibration test. In addition, no irreversible changes were observed for the compression test (using the machine apply and hold method) as deformations of approximately 127 mm were documented. The needle cartridges passed the visual inspection, internal pressure (bubble test), seal strength, and integrity – dye penetration tests. The validation test report is provided in Attachment 14C-1.

Induction Therapies' transport simulation of the Collagen P.I.N.'s needle cartridges in accordance with ISO 11607-1 "Packaging for terminally sterilized medical devices – Part 1 Requirements for materials, sterile barrier systems, and packaging systems." Samples were stressed using a transport simulation, according to ISTA 2A procedures. The tests were performed sequentially on the same shipping box. The shipping box remained unopened until the sequences of tests were completed. A visual inspection was performed after each sequence was finished. The following observations were noted for each test:

- Room Conditioning, including Extreme Cold Winter Conditioning and Elevated Temperature Summer Conditioning - no visible changes;
- Compression Test Machine Apply and Hold Method - Dents on carton box were observed. Large deformations of approximately 29.7, were documented;
- Vibration Test 1 (Random) - no visible changes were observed;
- Drop-Test - The box showed deformed drop corners and partially deformed drop edges after the test; and
- Vibration Test 2 (Random) - no visible changes were observed.

The ISO 11607 transport simulation test report is provided in Attachment 14C-2. The Collagen P.I.N.'s handpiece is labeled with a six-month shelf life.

In Vitro Study - Assessment of Needle Length, Penetration, and Cross-Contamination Risk

Induction Therapies conducted *in vitro* animal testing to verify the length of the Collagen P.I.N.'s needle, to assess their depth and rate penetration into skin, and to determine whether there is leakage and backflow through the needle cartridge silicone membrane into the device nosecone. This testing was conducting using the Collagen Pin's 36-needle cartridge on pig skin.

The testing showed the visible length for the 36-needle cartridge ranged from 1.959 mm to 2.833 which was within the manufacturer's specification of 3.0 mm. In addition, maximum skin penetration depth for the 36-needle cartridge was 2.866 mm (±0.047), which was within the manufacturer's specification of 2.5 mm. The test also showed that the maximum puncture duration (rate) of the needles was 0.180 seconds, which was within the manufacturer's specification of 0.180 seconds. Furthermore, there was no evidence of leakage or backflow. Thus, this study demonstrated that the Collagen P.I.N.'s needle cartridge met its specifications.

Animal Study – Assessment of Accuracy and Safety

Collagen P.I.N. conducted an *In Vitro histopathology* study, using two (2) pig specimens, to evaluate the accuracy and safety of the device's 36-pin needle cartridge. The test utilized eight (8) skin samples, one from the face, back, abdomen, and leg of each animal. The device was tested with and without ink. Ink was included as a mechanism to increase the visible assessment of microneedle accuracy.

The morphological analysis of the skin samples revealed small dermo-epidermal erosions secondary to punctures in all samples, and minor mononuclear inflammatory infiltrate of the papillary dermis in samples of abdomen and leg. The results and conclusions of this pig-skin histopathology report did not raise any different concerns or questions regarding safety and effectiveness – as related to the accuracy of the Collagen P.I.N. 36-pin microneedle cartridge.

Performance Data – Clinical

Induction Therapies sponsored a clinical study to evaluate the safety and effectiveness of Collagen P.I.N. as a treatment to improve the appearance of facial acne scars and nonfacial surgical or traumatic scars in adults with all Fitzpatrick Skin Types, aged 22 years and older. The clinical study was a nonsignificant risk, open-label, prospective, single-arm, two-site study in fifty subjects (n=50). The efficacy data from the subjects with facial acne scars (n = 25), as well the safety data from those subjects with nonfacial surgical or traumatic scars (n= 25), were used to demonstrate Collagen P.I.N.'s substantial equivalence for use in treating facial acne scars in the intended patient population.

Study Subjects

Eligible subjects were males or females at least 22 years of age of any race who had facial acne scars rated as mild to moderate (Grade 15 to 180) per the Échelle d'évaluation clinique des cicatrices d'acné (ECCA) acne scar scale or one non-facial trauma or surgical scar that was mild to moderate (score of 1 to 10) based on the Vancouver Scar Scale (VSS). The scars had to be amenable to microneedling and not have been treated with any alternative treatment modality within 6 months of the first study visit. Forty-seven of the subjects (94%) completed the study and 3 (6%) discontinued early.

Study Treatment

After washing the subject's skin in treatment area with Induction Therapies' Cleanse-It and applying DMC Medical Ltd.'s SupraGel to it, the investigators set the initial treatment depth by rotating the dial on the handpiece which has a scale from 0.0 mm to 3.0 mm in 0.1 mm increments. The investigator glided the tip perpendicular to the skin using a cross hatch motion (using horizontal and vertical movements) in the treatment area while applying gentle traction to the surrounding area. They gradually increased the needle depth until pinpoint bleeding was observed. Subjects were instructed to use Induction Therapies' Block-IT, which is a sunscreen, and Induction Therapies' Skin Renewal Hydrator after the treatment.

Subjects were treated with Collagen P.I.N. at Visit 1 (Day 1), Visit 2 (Day 30), Visit 3 (Day 60), and Visit 4 (Day 90). They were assessed for final efficacy and safety outcomes at Visit 5 (Day 150).

The mean number of treatments for subjects with facial acne scars was 3.7 of the planned 4 treatments. The maximum treatment depth ranged from 1.0 to 3.0 mm overall, with the mean ranging from 2.06 to 2.36 mm.

Study Endpoints and Statistical Analyses

Collagen P.I.N.'s efficacy was evaluated based on the following:

- Clinician Global Aesthetic Improvement Assessment (CGAIS): a 5-point scale from 1 (Very Much Improved) to 5 (Worse). The CGAIS was assessed in two ways - *i.e.*, live by the Investigator pre-treatment at Day 30, Day 60, Day 90 (pre-treatment), and Day 150 using pretreatment photographs as the baseline. In addition, CGAIS was graded by a panel of 2 board-certified dermatologists (noninvestigators) after the final visit using photographs taken pre-treatment at each visit. CGAIS success was the proportion of subjects for whom the appearance of their scars improved, *i.e.,* grade 1-3.
- Self-Assessed Scar Improvement Scale (SSIS): 6-point scale from -1 (Exacerbation of Scars) to 4 (75% to 99% improvement in appearance of acne scars).
- Subject Global Aesthetic Improvement Assessment (SGAIS): 5-point scale from 1 (Very Much Improved) to 5 (Worse).
- Subject Satisfaction: 5-point scale from 1 (Very Satisfied) to 5 (Very dissatisfied).

The primary population for efficacy analyses was the modified intent-to-treat ("mITT") population, which consisted of all subjects who received at least one study treatment and provided at least one post-treatment evaluation (n=48). The primary efficacy endpoint was CGAIS success in the mITT population.

The safety of Collagen P.I.N. was evaluated based on:

- Adverse Events (AEs), including treatment-emergent AEs ("TEAEs") and treatment-related AEs (TRAEs), serious adverse events ("SAEs"), unexpected adverse device effects ("UADEs"), and for TRAE by severity and relationship to study treatment.
- Investigator Tolerability Assessments on a scale of zero (none) to three (severe) of dryness, roughness of skin, tightness, erythema, and edema prior to each study treatment and 15 minutes following each treatment. The Investigator also asked the subject about itching and burning prior to and 15 minutes after treatment.
- Common Treatment Responses (CTR Diary) - the subjects recorded the following responses that typically occur following microneedling treatment in their CTR Diaries: redness, tightness, rough skin, dryness, tenderness, itching, burning, discomfort, and peeling.

Study Results:

Collagen P.I.N. improved the appearance of mild to moderate facial acne scars as assessed by the CGAIS, SSIS, SGAIS, and subject satisfaction. The primary efficacy endpoint of the proportion of subjects with CGAIS success at Visit 5 (Day 150) in the mITT population based on live assessment by the Investigator was 100% for subjects with facial acne scars (n=23) with no subject experiencing a worsening of their scars. The proportion of subjects with CGAIS success at Visit 5 in the mITT population graded by non- investigators 1 and 2, which was the other primary efficacy endpoint, was 47.8% and 60.9% for subjects with facial acne scars.

The proportion of subjects in the mITT population who reported at least a 25% improvement in the appearance of treated scars on the SSIS was 91.3% at Visit 5 (Day 150) for subjects with facial acne scars. The proportion of subjects in the mITT population who reported at least improvement on the SGAIS increased was 82.6% at Visit 5 (Day 150) for subjects with facial acne scars. The proportion of subjects reporting that they were satisfied or very satisfied increased was 91.3% at Visit 5 for subjects with facial acne scars. The increase in the proportion of subjects reporting improvement on the SSIS and on SGAIS are consistent with the CGAIS success assessed by the Investigator at Visit 5. The increase in subject satisfaction over time supports the investigator's CGAIS results.

Of the 50 treated subjects, 11 (22%) experienced one or more TEAEs during the study. Eleven of the 25 subjects with facial acne scars (44%) had a total of 12 TEAEs and none of the 25 subjects with nonfacial scars had a TEAE. Six of the 25 subjects with facial scars (24%) experienced one or more TRAEs during the study. The only TRAE was post-inflammatory pigment change; all of those events were mild or moderate and all 6 subjects who experienced TRAEs had Fitzpatrick skin type IV to VI. No SAEs and no UADEs were reported during the study and no subjects had study treatment temporarily or permanently discontinued due to AEs.

All of the treatment tolerability assessments were reported as none or mild pre-treatment by at least 96% of subjects on Days 1, 30, 60, and 90 post-treatment assessments of dryness, roughness of skin, itching, and burning were reported as none or mild for at least 94% of subjects. Tightness was assessed as none or mild post-treatment for 60% to 84% of subjects, moderate for up to 38% of subjects (Day 90), and severe for 2% on Day 90. Erythema was reported post-treatment as none or mild for 34% to 64% of subjects, moderate for up to 58% of subjects (Day 1), and severe for up to 11% (Day 30). Edema was reported post-treatment as none or mild for 62% to 78% of subjects, moderate for up to 38% of subjects (Day 60), and severe for up to 4% (Day 90).

A similar pattern was observed across most of the Common Treatment Responses ("CTRs"). From Day 1 to Day 7 after each visit, the proportion of subjects reporting none to mild CTRs generally increased, reaching 85% to 100% at Day 7. The severity of rough skin and peeling tended to increase for a few days before decreasing.

The results of this open-label study have shown that the Collagen P.I.N. improved the appearance of mild to moderate facial acne scars and was well-tolerated by all study subjects.

Conclusion

The Collagen P.I.N. has the same intended uses and similar indications and technological characteristics as SkinPen. Collagen P.I.N.'s slightly deeper maximum treatment depth, higher maximum puncture rate and slightly higher motor speed do not raise new questions of safety or effectiveness. Bench, animal, and clinical data demonstrate the safety and efficacy of Collagen P.I.N**.** for "use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, aged 22 years and older." Thus, Collagen P.I.N. is substantially equivalent to its predicate device for its proposed indication for use.