Sebacia, Inc.
Pedro Medrano
Acting Head of Regulatory Affairs
2905 Premiere Parkway, Suite 150
Duluth GA 30097

August 12, 2020

Re: K192620
Trade/Device Name: SNA-001 Silver Photoparticle Topical Gel
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser Surgical Instrument for use in General and Plastic Surgery and in Dermatology
Regulatory Class: Class II
Product Code: QCY
Dated: July 9, 2020
Received: July 16, 2020

Dear Pedro Medrano:

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,

Neil R.P. Ogden
Assistant Director, THT4A4
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192620

Device Name
SNA-001 Silver Photoparticle Topical Gel

Indications for Use *(Describe)*
SNA-001 Silver Photoparticle Topical Gel is indicated for use as an accessory to 810 nm diode laser for temporary removal of light-colored hair in patients with skin types I, II and III. Light-colored hair types include blonde, light red, light brown, gray and white.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) SUMMARY

510(k) Number: K192620

Submitter:

Sebacia, Inc.
2905 Premiere Parkway, Suite 150
Duluth, GA 30097

Contact: Pedro Medrano
Tel: 678-812-1103
Email: pmedrano@sebacia.com

Date Prepared: August 12, 2020

Device Information:

Trade Name:	SNA-001 Silver Photoparticle Topical Gel
Common Name:	Powered Laser Surgical Instrument
Device Class:	Class II
Classification Name:	Laser Absorbing Particles
Regulation Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulation No.:	878.4810
Product Code:	QCY
Prior Product Code:	GEX
Predicate Device:	ThermoLase® Softlight Carbon Lotion (K971207)

Device Description:

SNA-001 Silver Photoparticle Topical Gel (SNA-001) is used as an accessory to 810 nm diode dermatologic lasers for the removal of unwanted body hair. SNA-001 consists of near-infrared light-absorbing silver particles suspended in a topical gel that mediates selective photothermolysis of the hair follicle when illuminated by a specific wavelength of laser light (810 nm). The photoparticles are nanoscale silver plates coated with silica and tuned to a wavelength of 810 nm corresponding to commonly used dermatologic lasers. These photoparticles function as highly efficient chromophores for the absorption of laser light. When exposed to laser light of the appropriate wavelength, the photoparticles rapidly heat to temperatures capable of facilitating targeted damage to the hair follicle . SNA-001 is dark blue/black in color, is for single use only, and is provided non-sterile in 1cc polypropylene syringe dispensers.

Intended Use/Indications for Use:

SNA-001 Silver Photoparticle Topical Gel is indicated for use as an accessory to 810 nm diode laser for temporary removal of light-colored hair in patients with skin types I, II and III. Light-colored hair types include blonde, light red, light brown, gray and white.

Summary of Substantial Equivalence

SNA-001 and its predicate, ThermoLase® Softlight Carbon Lotion, have the same intended use, which encompasses the indication for use, as laser absorbing particles to be used in combination with an 810 nm diode laser for hair removal treatments. In relation to technological characteristics, SNA-001 and Thermolase lotion are comprised of different materials and delivery vehicles but the fundamental physical principle by which the two devices facilitate laser hair removal is identical. Both products are comprised of particles that absorb light from a laser and rapidly heat to temperatures capable of facilitating targeted injury to the hair follicle. As such, they are both chromophores. In dark-colored hair, the natural chromophore is melanin but in the case of light-colored hair, melanin is limited or even absent. SNA-001 acts as an exogenous chromophore to help facilitate the removal of light-colored hair with an 810 nm diode laser. Thermolase lotion is used in the same manner but with a Q-Switched 1064 nm Nd:YAG laser. The differences in technological characteristics are not material to the primary mechanism of action and do not raise additional questions of safety or efficacy as the key question is whether these exogenous particles can safely and effectively facilitate photothermal heating when used with the attendant dermatological laser. The non-clinical and clinical performance data demonstrate that SNA-001 is as safe and effective as the predicate device for its intended use.

Discussion of Performance Data

Non-Clinical Testing

SNA-001 was tested ex vivo for photothermal heating ability, biocompatibility (in accordance with ISO 10993-1), and shelf life. The established shelf life for SNA-001 is 18 months based on real-time stability testing data. A biodistribution study in a porcine model was conducted to evaluate the topical application of SNA-001 by vibration-assisted massage, followed by laser treatment, to analyze skin distribution and response. The results of the animal testing demonstrated that SNA-001 meets requirements for functionality and safety. The findings of the non-clinical testing demonstrated that SNA-001 Silver Photoparticle Topical Gel functions as intended, is biocompatible, and is as safe and effective as the predicate device for its intended use.

Clinical Studies

A multicenter, randomized, within-subject controlled clinical study with blinded assessment was conducted in the U.S. to evaluate the safety and effectiveness of SNA-001 when used as an accessory to 810 nm diode laser for the removal of unwanted light-colored facial and body hair (i.e., white, gray, blonde, light brown, or light red). A total of 77 subjects received treatment and were included in the Safety Population. Treatment and assessment areas on each subject were precisely defined on the left and right sides of one of the following three anatomical areas: face (upper lip/posterior neck), axilla, or bikini line. Of the 77 subjects treated, 65 were included in the Intent to Treat (ITT) Population and 49 were included in the Per Protocol (PP) population.

The majority of study subjects were female (96.9%) with a mean age of 45 years. All subjects were white, and the majority were not Hispanic or Latino. The distribution of Fitzpatrick skin type was 9.2% Type I, 61.5% Type II and 29.2% Type III. Subjects with light brown (33.8%) or blonde hair (32.3%) predominated with lesser percentages of subjects having light red (9.2%), white (9.2%), gray (3.1%), or a mixture of light hair colors (12.3%). Approximately 65% of the study subjects had treatment to the face (upper lip/posterior neck), while the remainder had treatment to the axilla (23.1%) or bikini line (12.3%).

The primary measure of effectiveness was the mean percentage change in hair count from baseline to 3 months post-treatment. Analyses of effectiveness were performed for ITT and PP Populations using

observed data, i.e., actual data collected without adjustment for missing values, as well as imputed data, i.e., actual data collected plus estimations for missing values. Multiple imputation (MI) methodology was used to estimate missing values. Statistical comparisons of the two treatments (SNA-001 + laser and Vehicle + laser) were prespecified to include both non-inferiority and superiority assessments.

The table below summarizes the mean percentage change in hair count from baseline to 3 months post-treatment using a) observed data for the ITT and PP Populations, and b) imputed data for the ITT and PP Populations. The primary effectiveness analysis of the difference between treatments met the prespecified non-inferiority criterion for the percentage change in hair count from baseline to 3 months post-treatment using MI for the ITT Population. Furthermore, the mean reduction in hair count was numerically higher for SNA-001 + laser than for Vehicle + laser in both the ITT and PP populations using MI and observed data but the differences were not statistically significant.

Mean Percentage Change in Hair Count from Baseline to 3 Months Post-Treatment

Analysis Population (Data)	SNA-001 + Laser (mean % change)	Vehicle + Laser (mean % change)
ITT (Observed)	-17.5	-1.1
ITT (MI)*	-16.5	-3.6
PP (Observed)	-25.4	-19.7
PP (MI)	-24.6	-13.9

NOTE: A negative number denotes reduction in hair count from baseline
*The analysis of the difference between treatments demonstrated non-inferiority of SNA-001 + laser to Vehicle + laser

In an analysis of the proportion of subjects achieving a defined percentage reduction in hair count (e.g., 10%, 20%, 30%, 40%, etc. reduction) at 3 months, there were generally more subjects achieving the target hair reduction in the SNA-001 + laser group than in the Vehicle + laser group. The differences between the two treatment groups weren't statistically significant except at 50% or greater hair reduction where a significantly greater proportion of subjects in the SNA-001 + laser group than in the Vehicle + laser group achieved the target (17.4% vs 8.7%; $p = 0.046$).

Safety data analyses demonstrated that treatment with SNA-001 was safe and well tolerated. Most reported adverse events in the treatment area were local dermatologic reactions of mild to moderate intensity, similar to those routinely observed with the use of dermatologic lasers. This included erythema, blistering, scabbing, bruising, rash, and a single report of skin pigmentation changes. These events resolved without sequelae; at 3 months post-treatment, there were no reports of adverse events in the treatment areas. Other reported adverse events (i.e., not in the treatment areas) were general illnesses, conditions, and complaints unrelated to study treatment. There were no serious and/or unanticipated adverse events related to study treatment.

Overall Conclusion

SNA-001 Photoparticle Topical Gel is indicated for use as an accessory to 810 nm diode laser for temporary removal of light-colored hair in patients with skin types I, II and III. Light-colored hair types include blonde, light red, light brown, gray and white. The non-clinical and clinical performance data support the substantial equivalence of SNA-001 to the predicate device for the proposed indications.