Sebacia, Inc.
% John Smith, Partner
Hogan Lovells US LLP
555 13th Street, NW
Washington, District of Columbia 20004

Re: K181518
Trade/Device Name: Sebacia Microparticles
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: June 8, 2018
Received: June 8, 2018

Dear John Smith:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/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 Ogden -S
2018.09.06 23:23:49 -04'00'

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
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)*

Device Name

Sebacia Microparticles

Indications for Use *(Describe)*

Sebacia Microparticles are indicated for use as an accessory to 1064 nm lasers to facilitate photothermal heating of sebaceous glands for the treatment of mild to moderate inflammatory acne vulgaris.

Type of Use *(Select one or both, as applicable)*

X Prescription Use (Part 21 C.F.R. § 801 Subpart D)

☐ Over-The-Counter Use (21 C.F.R. § 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) SUMMARY

SEBACIA, INC.

SEBACIA MICROPARTICLES

Submitter

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

Contact: Todd J. Meyer
COO & General Counsel
Phone: 678-417-7626
Email: tmeyer@tif.net

Date Prepared: June 7, 2018

Device Information

Device Name:	Sebacia Microparticles
Common Name:	Powered Laser Surgical Instrument
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in Dermatology
Classification Panel:	General & Plastic Surgery
Device Class:	Class II
Product Code:	QCY
Regulation:	21 C.F.R. § 878.4810

Predicate Devices

Sebacia Microparticles are an accessory to legally marketed 1064 nm medical lasers intended for dermatologic use, and specifically for the treatment of mild to moderate inflammatory acne vulgaris, such as the 1064 nm Nd:YAG Cutera CoolGlide Aesthetic Lasers (K153671).

The predicate device is the 1064 nm Nd:YAG Cutera CoolGlide Aesthetic Lasers (K153671). This device is one example of a legally marketed device meeting the specifications for use with the Sebacia Microparticles.

Device Description

Sebacia Microparticles are a non-sterile, single-use product that is topically applied to the face for the purpose of supporting and supplementing the performance of legally marketed 1064 nm medical lasers for dermatologic use. The liquid suspension contains microparticles comprised of a silica core wrapped in a gold shell and coated with polyethylene glycol. The Sebacia Microparticles are topically applied to the face followed by gentle agitation of the skin surface using a mechanical massager and irradiated with a commercially available 1064 nm laser that heats the microparticles resulting in localized selective photothermolysis. The legally marketed 1064 nm medical laser used with the Sebacia Microparticles must meet the following specifications:

- Fluence ranging from 20 J/cm2 to 35 J/cm2
- Pulse duration of 30 ms
- At least 5-15mm spot size

Intended Use / Indications for Use

Sebacia Microparticles are indicated for use as an accessory to 1064 nm lasers to facilitate photothermal heating of sebaceous glands for the treatment of mild to moderate inflammatory acne vulgaris.

Performance Data

Nonclinical Testing

Sebacia Microparticles were tested ex vivo for photothermal heating ability, biocompatibility (in accordance with ISO 10993-1) and shelf life. All results met predetermined performance criteria. The established shelf-life for the product is two (2) years based on real-time stability testing data. Three animal studies in a porcine model were performed to evaluate formulation and laser parameters, as well as safety, prior to the commencement of clinical testing. The results of animal testing demonstrate that Sebacia Microparticles meet prospective product requirements for functionality and safety.

Clinical Studies

A randomized, controlled, parallel group, clinical study with blinded assessment was conducted in the U.S. to evaluate the Sebacia Microparticles when used with a 1064 nm Nd:Yag laser in facial mild to moderate inflammatory acne vulgaris. A total of 168 subjects received treatment, with approximately half of the subjects receiving the Sebacia Microparticles with laser ("SM + Laser") treatment and the other half receiving Laser Alone. Results are summarized in the table below:

EFFECTIVENESS AND TREATMENT PARAMETER RESULTS

	SM + Laser (n = 86)	**Laser Alone (n = 82)**
PRIMARY ENDPOINT		
% reduction in ILC (Baseline to Week 12); mean	40.17	41.89
% reduction in ILC (Baseline to Week 12); median	53.33	45.45
SECONDARY ENDPOINTS		
% with ≥ 40% ILC reduction at Week 12	64.4	56.5
% with IGA clear/almost clear at Week 12	30.1	31.9
absolute reduction in ILC (Baseline to Wk 12); mean	8.4	8.5
absolute reduction in ILC (Baseline to Wk 12); median	11.0	9.0
TREATMENT PARAMETERS		
laser fluence (J/cm^2); mean	29.44	48.93
laser fluence (J/cm^2); median	30.00	49.79
number of treatment sessions (All Patients); mean	2.9	5.3
number of treatment sessions (All Patients); median	3.0	6.0
number of treatment sessions (Completers); mean	3.0	5.8
number of treatment sessions (Completers); median	3.0	6.0

ILC = inflammatory lesion count

Percentage reduction in inflammatory lesion count from Baseline to Week 12 was assessed, revealing similar acne treatment effects for each group. Analyses of the secondary endpoints were supportive of the primary effectiveness analyses with results indicative of similar acne treatment effects for

SM + Laser when compared to Laser Alone. Summary results for subject satisfaction revealed that more subjects reported “Complete Improvement” or “Marked Improvement” in the SM + Laser treatment group than in the Laser Alone group. Analyses of overall mean fluence and the number of treatment sessions clearly demonstrated that use of fewer treatments and lower laser fluences in the SM + Laser Group resulted in equivalent reduction in mild to moderate inflammatory acne lesions when compared to the reduction in the Laser Alone Group.

Treatment with the Sebacia Microparticles also demonstrated a positive safety profile. The most frequent adverse events reported in both treatment groups were primarily general illnesses and complaints that were unrelated to study treatment. Furthermore, over 90% of the AEs reported in each treatment group were unrelated to study treatment. All reported AEs, regardless of study treatment were of mild to moderate intensity. There were no severe AEs nor were there any serious and/or unanticipated adverse events related to study treatment.

Conclusions

Sebacia Microparticles are indicated for use as an accessory to 1064 nm lasers to facilitate photothermal heating of sebaceous glands for the treatment of mild to moderate inflammatory acne vulgaris. In sum, the non-clinical and clinical data support the substantial equivalence of the Sebacia Microparticles to the predicate device for the proposed indications.