Strata Skin Sciences, Inc.
℅ Paul Dryden
President - consultant to Strata Skin Sciences
Strata Skin Sciences, Inc. c/o ProMedic, LLC
131 Bay Point Dr. NE
St. Petersburg, Florida 33704

Re: K193478
Trade/Device Name: XTRAC Momentum Excimer Laser System, Model AL10000
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: GEX
Dated: December 11, 2019
Received: December 16, 2019

Dear Paul Dryden:

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 and Part 809; 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,

Jessica Mavadia-Shukla, Ph.D.
Acting 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K193478

Device Name

XTRAC Momentum Excimer Laser System, Model AL10000

Indications for Use *(Describe)*

UVB phototherapy for psoriasis, vitiligo, atopic dermatitis, and leukoderma.

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

XX 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.

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Date Prepared: 14-Jan-2020

I Submitter

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Senior Quality / Regulatory Manager

Submission Correspondent: Paul Dryden
ProMedic, LLC

II Device

Proprietary or Trade Name:	XTRAC Momentum Excimer Laser System, Model AL10000
Common/Usual Name:	Powered laser surgical instrument
Classification Name:	Laser surgical instrument for use in general and plastic surgery and in dermatology (21 CFR 878.4810)
Regulatory Class:	II
Product Code:	GEX

III Predicate Device:

K073659 - XTRAC Velocity Excimer Laser System, Model AL10000

IV Device Description:

The Momentum is a self-contained compact laser light source that operates on standard AC supply power requiring no special power or cooling considerations. A protective interlocked housing encloses the laser source, electronics, and gas storage and distribution system. The XTRAC Momentum Model AL10000 comes in two spatial configurations: a horizontal (Velocity)configuration and a vertical (upright / Momentum) configuration.

A core element of both the Momentum excimer laser and the Velocity is a sealed chamber containing a mixture of pressurized Neon, Xenon, and HCl gases. High-voltage electrical discharges into the gas mixture create unstable XeCl molecules, which dissociate rapidly, creating monochromatic ultraviolet light at a wavelength of 308 nm. The electrical discharges are repeated in a fast sequence, producing a train of light pulses of a nominal duration of 30ns each. The timing of electrical discharges and energy of the produced light are constantly monitored by an on-board microprocessor to ensure safety.

Using a set of optical devices such as mirrors, shutters, lenses, and optic fibers, the produced light is focused and directed by the user to skin areas affected by disease. Each dose delivered by the system is composed of multiple laser pulses delivered at a preset repetition rate for a duration that is managed by the system processor.

Maximum pulse energy delivered to the patient's skin through the fiber optic cable and subsequent hand piece with skin contact tip is 15mJ per pulse or a fluence (radiant exposure) of 3.8 mJ/cm^2 (non-ablating). The average power delivered to the patient's skin is limited to 6 Watts which is a balance between time to deliver a dose and skin heating effect.
Accessories include different tip configurations:

- Standard Tip: Designed to pass a fixed 4cm^2 square beam.
- Short Tip: For use with the iris diaphragm
- Short Hair Scalp Tip: Similar to the standard tip but includes three hollow elongated "teeth" to comb and part the hair in order to expose the scalp.
- Multi-Micro Dose (MMD) Tip: Provides four different dose levels with a single beam application, which can assist the physician in selection of the initial treatment dose.

V Indications for Use:

UVB phototherapy for psoriasis, vitiligo, atopic dermatitis, and leukoderma.

Environments of use: Healthcare facilities and outpatient dermatology clinics

VI Modifications

The subject device includes modifications to the predicate. These modifications include:

- **Mechanical:** Change to a vertical the footprint.
- **Short Hair Scalp Tip:** A patient-contact accessory - Short Hair Scalp Tip is specifically designed to treat lesions on the scalp.
- **Finger Switch:** A finger switch was added to the handpiece on the liquid-light guide (LLG) so the user could operate the laser by pressing a button rather than stepping on a footswitch.
- **Patient Database:** An on-board electronic database was added to store patient treatment data as a complement to the written treatment log template provided by Strata to the clinician.
- **MMD Tip Usage:** Software updated to accommodate the MMD tip accessory, cleared under K181480, is used to help determine the Optimal Therapeutic Dose (OTD) value when treating a new lesion.
- **Cool Beam:** The cool beam feature provides a means of reducing laser power within a treatment session at the clinician's discretion while maintaining the same dose accuracy as nominal laser power.
- **Maximum Dose of 5000 mJ/cm^2:** The maximum dose level for the predicate Velocity is 4,500mJ/cm^2 but data regarding a maximum dose level of 5,000 mJ/cm^2 was provided. Dose selection guidelines have not changed, and the accuracy of all dose levels is maintained by the same closed-loop control as the predicate.

VII Comparison of Technological Characteristics and Performance with the Predicate

Table 1 is a comparison – Subject Device vs. the Predicate, K073659 including technological characteristics and performance.

Table 1: Comparison of the *Velocity* AL10000 laser to the modified device

CHARACTERISTIC	Predicate Device	Subject Device
Device name	XTRAC *Velocity* Excimer Laser System Model AL10000	XTRAC *Momentum* Excimer Laser System Model AL10000
FDA approval	K073659	N/A
Indications for use	UVB Phototherapy for psoriasis, vitiligo, atopic dermatitis, and leukoderma	UVB Phototherapy for psoriasis, vitiligo, atopic dermatitis, and leukoderma
Patient population	Adults	Adults
Environments for use	Primary healthcare facilities (typically dermatology clinics and offices)	Primary healthcare facilities (typically dermatology clinics and offices)
Type of use	Prescription	Prescription
Technological Characteristics and Performance Specifications		
Photon source	XeCl Excimer laser	XeCl Excimer laser
UV spectrum	UVB	UVB
Wavelength (nm)	308	308
Optical pulse width – FWHM (ns)	30	30
Maximum power to tissue (W)	6.0	6.0
Maximum Dose	4,500 mJ/cm^2	5,000 mJ/cm^2
Maximum pulse repetition rate (Hz)	400	400
Maximum energy to tissue per pulse (mJ)	15	15
Maximum laser energy output (mJ)	40.0	40.0
Delivery system	Liquid fiber-optic (LLG) with user-directed hand piece	Liquid fiber-optic (LLG) with user-directed hand piece
Exposure type	User-directed to target area only	User-directed to target area only
Patient-contacting parts	Removable/reusable plastic tip	Removable/reusable plastic tip
Exposure control	Microprocessor with hard-wired switch	Microprocessor with hard-wired switch

Table 2: Differences between the Momentum AL10000 laser and the predicate device

FEATURE	PREDICATE K073659	Modified DEVICE	REASON
Finger-controlled laser exposure	Not available	Integrated into the delivery handpiece	User preference
Footswitch for exposure control	Mandatory	Not available	User preference
Device configuration	Horizontal only	Horizontal, Vertical	User preference
Short-Hair Scalp tip	Not available	Available	User preference
Selectable dose range (mJ/cm^2)	100 - 4,500	50 – 5,000	User preference
Power level during treatment	One power level available (always ≤ 6W)	Two power levels available: normal (always ≤ 6W) and reduced (approximately 2.8W)	Enhanced safety (less heating of the skin)
On-board database	Not available	Available	User preference
MMD tip support	Not available	Available	User preference

VIII Performance Data

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility –
The modifications do not change the materials in patient contact. The patient contacting materials are identical to the predicate and review of the geometry and processing did not raise new or different concerns.

Electrical Safety and EMC
Electrical safety and EMC testing were conducted on the subject device. The system complies with AAMI ANSI ES 60601-1: 2005 + A1: 2012 and IEC 60601-2-22 Edition 3.1 2012-10 standards for safety and IEC 60601-1-2: 2014 for EMC.

Software Verification and Validation Testing
Software verification and validation testing were conducted. The software for this device was considered as a "moderate" level of concern.

Mechanical, Animal, and Clinical Testing
No mechanical, animal or clinical testing was performed.

IX Conclusions

Discussion of Differences –
The identified differences do not raise new or different concerns of safety or effectiveness relative to the predicate.

Substantial Equivalence Conclusion
The performance testing has demonstrated that the subject devise met the applicable standard performance requirements. The sponsor has demonstrated through performance testing, design

and features, and non-clinical testing that the proposed device and predicate have been found to substantially equivalent.