December 29, 2022

Solta Medical, Inc.
℅ Prithul Bom
Most Responsible Person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K223647
Trade/Device Name: CLEAR+BRILLIANT TOUCH® Laser System
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, ONG
Dated: December 5, 2022
Received: December 6, 2022

Dear Prithul Bom:

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,

Jessica Carr -S

for Jianting Wang
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223647

Device Name
CLEAR+BRILLIANT TOUCH® Laser System

Indications for Use *(Describe)*
The CLEAR + BRILLIANT TOUCH® System is indicated for use in dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures.

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.

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Department of Health and Human Services
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"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."

Summary Preparation Date: December 27, 2022

1. **510(k) Owner Name and Address**

Solta Medical, Inc.
11720 North Creek Parkway N, Suite 100
Bothell, WA 98011 USA

Submitter & Primary Contact:
Aditi Chaubal (primary contact)
Phone: 425-420-2350
Fax: 1-425-420-2300
aditi.chaubal@solta.com

2. **Identification of Subject Device**

Trade Name:	CLEAR+BRILLIANT TOUCH® Laser System
Common Name:	Powered Laser Surgical Instrument with Microbeam\Fractional Output
Regulation Number:	21 CFR 878.4810
Product code:	GEX, ONG
Device Panel:	General & Plastic Surgery
Device Classification:	Class II

3. **Predicate Device**

Trade Name:	CLEAR+BRILLIANT® Laser System
Common Name:	Powered Laser Surgical Instrument with Microbeam\Fractional Output
Regulation Number:	21 CFR 878.4810
Product code:	GEX, ONG
Device Panel:	General & Plastic Surgery
Device Classification:	Class II
510(k) Number:	K120433, K110349

4. **Device Description**

The CLEAR + BRILLIANT TOUCH® Laser System is the second generation of the Clear+Brilliant line of products. Clear+Brilliant products use non-ablative laser designed for use in dermatological procedures intended to improve the appearance of a patient's skin. The system incorporates self-diagnostic algorithms to ensure its correct operation. The CLEAR +

BRILLIANT TOUCH® Laser System is part of the family of Solta Medical products using the fractional photothermolysis principle to resurface the skin.
CLEAR + BRILLIANT TOUCH® Laser System is comprised of four sub-systems:

1. Console
2. Handpieces: 1440nm and 1927nm (Perméa) handpieces
3. Treatment Tip
4. Credit Key

The console and up to two handpieces are connected mechanically and electrically by an umbilical cable. The treatment tip is mechanically and magnetically secured to the handpiece. All components must be properly connected and fully functional for the system to be operable. The system will not permit laser energy output until the treatment tip is in contact with the patient's skin.

The embedded processor and software control the precise delivery of the fractional laser treatment by directing the electrical and mechanical components that determine the position, spacing, and focus of the optical output. The processor and software also monitor the status of a treatment and the system and present this information to the operator on the touchscreen.

The Credit Key is the replaceable accessory allowing access to treatment credits and is attachable to the console. It is removable and is disposed of after the credit balance reaches zero.

The solid-state design of CLEAR + BRILLIANT TOUCH® Laser System limits maintenance and minimizes utility requirements.

5. Indications for Use

"*The CLEAR + BRILLIANT TOUCH® Laser System is indicated for use in* dermatological procedures requiring the coagulation of soft tissue and general skin resurfacing procedures."

6. Comparison of Technological Characteristics

The CLEAR+BRILLIANT TOUCH® Laser System and accessories share similar device operation, overall technical and functional capabilities. The design, function and treatment delivery are equivalent to the predicate device.

Summary of the technological characteristics

Feature	**CLEAR+BRILLIANT (Predicate – K120433)**	**CLEAR+BRILLIANT Touch® (Subject Device)**	**Remark**
Product Code & Reg. Classification	GEX/ONG, Class II	GEX/ONG, Class II	Equivalent
Laser Classification	Class III-R	Class III-R	Equivalent
Indications for Use	The Clear + Brilliant Laser System is intended for dermatological procedures requiring the coagulation of soft tissue and	*The CLEAR + BRILLIANT TOUCH® System is indicated for use in* dermatological procedures requiring	Equivalent

	general skin resurfacing procedures.	the coagulation of soft tissue and general skin resurfacing procedures.	
HandPiece			
Laser Type	Diode Laser	Diode Laser	Equivalent
Wavelength, nm	1440 1927	1440 1927	Equivalent
Peak Laser Power, W	1440nm: 2.5 Watts 1927nm: 0.9 Watts	1440nm: 2.5 Watts 1927nm: 0.9 Watts	Equivalent
Electrical	110-240V- AC	110-240V- AC	Equivalent
Skin Cooling Method	Passive Conductance	Passive Conductance	Equivalent
Main Components	Console, hand piece(s), Treatment Tips	Console, hand piece(s), Vented Treatment Tips	Equivalent
Laser Activation in Hand or Foot Activated	Hand switch activated	Hand switch activated	Equivalent
Treatment Tip			
Tip Design	No vents	Vented	Difference
Material	Polycarbonate GE HPH4404, translucent grey (Polycarbonate)	Americhem FRPC300 L32721, grey tinted (Polycarbonate)	Difference, but no new biocompatibility safety concerns.
Console			
User Interface	LCD	Touchscreen Technology for user interaction	Difference
Number of handpiece cradles	1	2	Difference
Handpiece to console connection	Manually fastened screws	Mechanical Latch	Difference
Number of Handpieces connected during operation	1	2	Difference
Treatment Authentication			
Authenticator	SmartCard	Credit Key	Difference
Authenticator Use	Different SmartCard for different Handpieces	Same credit key for both Handpieces	Difference
Dimensions			
Console Dimensions (Heights, Width, Depth)	17.62"x12.47"x 8.03"	12.5” W x 11.25” H x 11” D (dimensions of the system with two stowed handpieces)	Difference
Hand Piece Dimensions (Height, Width, Depth)	8.3"x3.1"x2.0"	8.3"x3.1"x2.0"	Equivalent
Weight	Approximately 15 lbs.	Approximately 15.6 lbs. (weight of system with two stowed handpieces and credit key installed on console)	Equivalent

Hand Piece Weight	330 grams or approximately 0.7 lbs.	330 grams or approximately 0.7 lbs.	Equivalent
Treatment			
Density	1927nm: 20-40 microthermal zone punctures 1440nm: 40-60 micro thermal zone punctures per cm2 per pass	1927nm: 20-40 microthermal zone punctures 1440nm: 40-60 micro thermal zone punctures per cm2 per pass	Equivalent
Treatment coverage based on Lesion Cross Section and Density	Approximately 4% to 12%	Approximately 4% to 12%	Equivalent
Treatment width	10 mm	10 mm	Equivalent
Operating Conditions			
Operating Conditions: Temperature	59 to 86-degree F (15 to 30 degree C)	59 to 86-degree F (15 to 30 degree C)	Equivalent
Operating Conditions: Relative Humidity	30-75%, Non-condensing	30-75%, Non-condensing	Equivalent
Operating Conditions: Altitude	<10, 000 Feet (<3,075 Meters)	<10, 000 Feet (<3,075 Meters)	Equivalent

The CLEAR+BRILLIANT TOUCH® Laser System is developed on the Solta System Controller (SC) platform. This platform comprises hardware, firmware, and software (SW) which are common across different Solta products. This architecture is consistent with the Solta New Product architecture. The software portion of this architecture is split into two portions.

1. System controller software (SC)
2. CLEAR+BRILLIANT TOUCH® Laser System software

The System Controller software is responsible for Operating System (OS) functions and common product functions (across products such as infrastructure). This is a software component that implements common functions across products implemented at Solta Medical. This is shared as source code between the various products and will be included in the CLEAR+BRILLIANT TOUCH® Laser System software build.

7. Non-Clinical Performance Testing

As with the predicate device, safety tests of the CLEAR+BRILLIANT TOUCH® Laser System has also demonstrated its compliance with applicable requirements of the following standards:

Basic Safety and Essential Performance – General, Particular, and Collateral

Document No.	Document Title
ANSI/AAMI ES 60601-1(2005) + AMD (2012) and AAMI STD ES60601-1.	Medical electrical equipment – Part 1: General requirements for basic safety and essential performance

Document No.	Document Title
IEC/EN 60601-1-2 Ed.4.0 (2014)	Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests
IEC 60601-2-22:2012, Edition 3.1	Medical Electrical Equipment—Part 2-2: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment.
IEC 60825-1:2014 Edition 3.0	Safety of laser products – Part 1: Equipment classification and requirements.

Biocompatibility

Document No.	Document Title
ISO 10993-1:2018	Biological evaluation of medical devices -- Part 1: Evaluation and testing within a risk management process
EN/ISO-10993-5: 2009	International Organization for Standardization (ISO) 10993-5, Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity.
ISO 10993-10:2013	International Organization for Standardization (ISO) 10993-10, Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization (2010).

Management

Document No.	Document Title
21 CFR Part 820	FDA Quality Systems Regulation
ISO 13485	Medical Devices – Quality Management Systems
EN ISO 13485:2016	Medical devices—Quality management systems—Requirements for regulatory purposes
EN ISO 14971:2019	Medical Devices—Application of risk management to medical devices
EN 62304:2015	Medical device software—Software life cycle processes

Human Factors and Usability Engineering

Document No.	Document Title
EN/IEC 62366-1 b: 2015 Edition 1.0 b cor.1: 2016	Medical devices - Application of usability engineering to medical devices
IEC 60601-1-6:2013, Edition 3.1	Medical electrical equipment -- Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability.
ANSI/AAMI HE75: 2009 (R)2018 (Reference Standard)	Human factors engineering—Design of medical devices

Safe Transit

Document No.	Document Title
ISTA testing standards	International Safe Transit Association; Packaging integrity performance tests; General test standards are ISTA 1A, 2A, and 3A per transport environment.

The CLEAR+BRILLIANT TOUCH® Laser System passed all the above applicable standards testing. The product performance testing demonstrates that the functional requirements have been met and that CLEAR+BRILLIANT TOUCH® Laser System is equivalent to the predicate device.

8. Conclusion

The CLEAR+BRILLIANT TOUCH® Laser System shares the same design and functional features as the predicate device, including the laser type, wavelength and device design. Therefore, the CLEAR+BRILLIANT TOUCH® Laser System is substantially equivalent to the previously cleared version of the CLEAR+BRILLIANT Laser System.