July 10, 2024

Solmedix Co., Ltd
% Dave Kim
Medical Device Regulatory Affairs
Mtech Group
7505 Fannin St. Ste 610
Houston, Texas 77054

Re: K232177
Trade/Device Name: Lightin System (Lightin, Lightin Generator)
Regulation Number: 21 CFR 874.4420
Regulation Name: Ear, Nose, And Throat Manual Surgical Instrument
Regulatory Class: Class I
Product Code: SBS, EQH
Dated: June 12, 2024
Received: June 12, 2024

Dear Dave Kim:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT Devices

OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K232177

Device Name
Lightin System (Lightin, Lightin Generator)

Indications for Use *(Describe)*

Lightin is a needle for injection laryngoplasty with an optical fiber.
Lightin Generator is an AC-powered light source including Light Guide which is fiber optic cable that transmits light at the tip of fiber optics embedded within Lightin.
Lightin System is used for injection laryngoplasty to address glottic incompetence to indicate the injection site with visible light.

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

K232177

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of 21 CFR §807.92.

1. Date: June 4, 2024

2. Manufacturer and 510(k) Sponsor

- Name: Solmedix Co., Ltd.
- Address: #706, 330, Seongarm-ro, Mapo-gu, Seoul, 03920 Republic of Korea
- Contact Name: Hyeroung Lee (Ms) / RA Part Leader
- Telephone number: +81-2-3153-7717
- E-mail address: hrlee@solmedix.com

3. Submission Correspondent

- Name: Dave Kim, MBA
- Company Name: Mtech Group LLC
- Address: 7505 Fannin St. Suite 610, Houston, TX 77054, USA
- Telephone number: 713-467-2607
- E-mail address: davekim@mtechgroupllc.com

4. Device Identification

The subject device is comprised of the following components:

Trade Name	Lightin
Device Classification Name	Set, Laryngeal Injection
Regulation Number	21CFR§874.4420
Regulation Class	Class I
Classification Product Code	SBS
Classification Pannel	Ear Nose & Throat

Trade Name	Lightin Generator
Device Classification Name	Source, Carrier, Fiberoptic Light
Regulation Number	21CFR§874.4350
Regulation Class	Class I
Classification Product Code	EQH
Classification Pannel	Ear Nose & Throat

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5. Legally Marketed Predicate Device

Predicate Device #1

Manufacturer	Aspen Surgical Products, Inc.
Trade Name	Symmetry Surgical
510(k)	510K Exempt (CL 1)
Regulation Number	21CFR§874.4420
Regulation Class	Class I
Product Code	KAA
Classification Pannel	Ear Nose & Throat

Predicate Device #2

Manufacturer	AESCULAP AG
Trade Name	AESCULAP® LED LIGHT SOURCE
510(k)	510K Exempt (CL 1)
Regulation Number	21CFR&874.4350
Regulation Class	Class I
Classification Product Code	EQH
Classification Pannel	Ear Nose & Throat

Reference Device #1

Manufacturer	Peregrine Surgical Ltd
Trade Name	23ga and 25 ga Adjustable Chandelier Illuminator
510(k)	K151604
Regulation Number	21CFR&876.1500
Regulation Class	Class II
Product Code	MPA
Classification Pannel	Ear Nose & Throat

Reference Device #2

Manufacturer	Zhejiang Kindly Medical Device Co., Ltd.
Trade Name	Sterile Hypodermic Needles for Single Use
510(k)	K233037
Regulation Number	21 CFR&880.5570
Regulation Class	Class II
Product Code	FMI
Classification Pannel	General hospital

6. Device Description

Lightin System consists of Lightin and Lightin Generator.

Lightin is a light-guided needle used injection laryngoplasty and Light generator delivers the light energy to Lightin by generating LED light from an AC-powered light source.

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Lighin consists of injection needle, Y-connector and SMA connector/cable.

The light transmitted from the Lightin Generator is emitted from the tip of fiber optics embedded within Lightin.

Lightin system used for injection laryngoplasty procedures to indicate the injection site with visible light. This system does not contain or deliver drugs.

7. Indications for Use

Lightin is a needle for injection laryngoplasty with an optical fiber.

Lightin Generator is an AC-powered light source including Light Guide which is fiber optic cable that transmits light at the tip of fiber optics embedded within Lightin.

Lightin System is used for injection laryngoplasty to address glottic incompetence to indicate the injection site with visible light.

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8. Comparison Table of Technological Characteristics with the predicated device

A. Lightin

Attribute	Predicate Device #1	Proposed device	Remark
Product name	Symmetry Surgical	Lightin, Lightin System	
510(k) no	510K Exempt (CL 1)	K232177	
Product Code	KAA	SBS	
Manufacturer	Aspen Surgical Products, Inc.	Solmedix Co., Ltd	
Indications for use	An ear, nose, and throat manual surgical instrument is one of a variety of devices intended for use in surgical procedures to examine or treat larynx. This generic type of device includes laryngeal injection set.	Lightin is a needle for injection laryngoplasty with an optical fiber. Lightin generator is an AC-powered light source including Light Guide which is fiber optic cable that transmits light at the tip of fiber optics embedded within Lightin. Lightin System is used for injection laryngoplasty to address glottic incompetence to indicate the injection site with visible light.	**Similar** Predicate Device #1 and Lightin is the same as that used for laryngeal injection. Lightin uses LED light to indicate the injection site and the LED source emits light through the PMMA fiber in the needle. Considering the application area and the indications for use, Lightin has less risk than the predicate device.

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Appearance	No information		**Similar** The needle tip resembles an injection needle, **Different** inclusion of a light-transmitting fiber
Jacket Material	N/A	PVC	**Different** Fiber optic cable is not included in the primary predicate device (#1). The subject device has fiber optics inserted in the needle. The jacket materials protecting the fiber optic of both devices are commonly used.
Jacket Color	N/A	Blue Orange	**Similar** Jacket is color coded for needle identification. Color coding was applied to Lightin according to the needle gauge standard.
Illumination Fiber – OD	N/A	0.125mm (0.004521”)	**Different** PD #1: No optic fiber Lightin uses LED light to indicate the injection site and the LED source emits light through the PMMA fiber in the needle. Considering the application area and the indications for use, Lightin has less risk than the predicate device.
Illumination Fiber Material	N/A	PMMA (Polymethyl methacrylate with Fluorinated Polymer Cladding)	**Different**
Needle size	No information	1. 23G 2. 25G	
Needle Material	No information	304 stainless Steel	

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Reusable/ Disposable	No information	Disposable	
Sterilization	No information	EO	

Reference Device #1: K151604

Attribute	Reference device #1	Proposed device	Remark
Product name	23ga and 25ga Adjustable Chandelier Illuminator	Lightin, Lightin System	
510(k) no	K151604	K232177	
Product Code	MPA	SBS	
Manufacturer	Peregrine Surgical, Ltd	Solmedix Co., Ltd	
Indications for use	Adjustable Chandelier Illuminator family of ophthalmic illuminators is for wide angle illumination during ophthalmic surgery.	Lightin is a needle for injection laryngoplasty with an optical fiber. Lightin generator is an AC-powered light source including Light Guide which is fiber optic cable that transmits light at the tip of fiber optics embedded within Lightin. Lightin System is used for injection laryngoplasty to address glottic incompetence to indicate	**Similar** For the reference #1, the main Indication for use is for wide-angle illumination during ophthalmic surgery. However, Lightin uses LED light to indicate the injection laryngoplasty site. Although there is a difference such as in the indication for use, Reference #1 and Lightin have similar technical characteristics in that the LED source emits light through the PMMA fiber in the needle.

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		the injection site with visible light.	
Appearance			**Similar** For Reference #1, its needle tip resembles an injection needle, and its inclusion of a light-transmitting fiber is similar.
Jacket Material	PTFE (Polytetrafluoroethylene)	PVC	**Similar** The Reference #1 device has fiber optics inserted in the needle**,** same as Lightin. The jacket materials protecting the fiber optic of the two devices are different, but both are commonly used.
Jacket Color	Black/Green Black/Blue	Blue Orange	**Similar** Jacket is color coded for needle identification. Color coding was applied to Lightin according to the needle gauge standard.
Illumination Fiber – OD	0.015”	0.125mm (0.004521”)	**Different** The difference of the illumination fiber outer diameter (O.D.) is due to the functional

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			characteristics of the two devices. Reference #1 is used for wide-angle illumination and Lightin is used for marking the injection laryngoplasty site. Due to this functional difference, the illumination fiber OD of the reference #1 is bigger than that of Lightin.
Illumination Fiber Material	PMMA (Polymethyl methacrylate with Fluorinated Polymer Cladding)	PMMA (Polymethyl methacrylate with Fluorinated Polymer Cladding)	**Same**
Needle size	1. 23G 2. 25G	1. 23G 2. 25G	**Same**
Needle Material	304 stainless Steel	304 stainless Steel	**Same**
Reusable/ Disposable	Disposable	Disposable	**Same**
Sterilization	EO	EO	**Same**

Reference Device #2: K233037

Attribute	Reference Device #2	Proposed device	Remark
Product name	Sterile Hypodermic Needles for Single Use	Lightin, Lightin System	
510(k) no	K233037	K232177	
Product Code	FMI	SBS	
Manufacturer	Zhejiang Kindly Medical Device Co., Ltd.	Solmedix Co., Ltd	
Indications for use	Sterile Hypodermic Needle for Single Use are intended for use with syringes and injection devices for	Lightin is a needle for injection laryngoplasty with an optical fiber. Lightin generator is an AC-powered light	Similar Reference Device #2 and Lightin are same as injection needles for a single

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	general purpose fluid injection/aspiration.	source including Light Guide which is fiber optic cable that transmits light at the tip of fiber optics embedded within Lightin. Lightin System is used for injection laryngoplasty to address glottic incompetence to indicate the injection site with visible light.	use. Lightin is used for laryngeal injection and RD #2 is used as an injection device for general purpose. Lightin has narrower indication of use than RD#2.
Needle size	14G~34G	1. 23G 2. 25G	Similar
Needle Material	304 Stainless Steel	304 Stainless Steel	Same
Reusable/ Disposable	Disposable	Disposable	Same
Sterilization	EO	EO	Same
Performance Specification	ISO7864 ISO9626 ISO80369-7 ISO8039-20	ISO7864 ISO9626 ISO80369-7 ISO8039-20	Same

B. Lightin Generator

Attribute	Predicate device #2	Proposed device	Remark
Product name	AESCULAP® LED LIGHT SOURCE	Lightin Generator, Lightin System	
510(k) no	510K Exempt (CL 1)	K232177	
Product code	EQH	EQH	**Same**
Manufacturer	AESCULAP, AG.	Solmedix co., Ltd	

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Indications for use	The device is intended for use in endoscopy systems for human medicine. In combination with a light lead, endoscope, camera and monitor, its purpose is to illuminate the inside of the human body.	Lightin generator is an AC-powered light source including Light Guide which is fiber optic cable that transmits light at the tip of fiber optics embedded within Lightin.	**Similar** Predicate Device #2 and Lightin Generator are the same light sources that generate LED light. Lighitin Generator, its intended use is restricted solely to Lightin for injection laryngoplasty. Lightin Generator is used to transmits light at the tip of fiber optics embedded within Lightin for injection laryngoplasty. Both PD #2 are technically identical with Lightin Generator.
Appearance			**Similar**
Light Source	LED	LED	**Same**
Design	Dimension: 330 * 146 * 367 mm Weight: 8.5kg	Dimension: 300 * 200 * 100 mm Weight: 2.7kg(excluding adapter)	-
Accessories	Sterile Adapter 	Adapter(Power Cord)	**Same** PD #2 has a cable to connect to the LED light source, and Lightin Generator has a Light Guide for the same purpose. **Different** The adapter of PD #2 is compatible to connect various optical fiber cables to the

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	Optical Cable Power cord	 Light Guide 	LED light source, but the Lightin Generator is exclusive to Lightin, so no compatible parts are required.
Technical Specification	Output (at the end light guide) : 240W	Output (at the end light guide): ≤ 8mW	**Different** The output of PD #2 is higher than that of Lightin Generator because PD #2 uses the LED light to illuminate the board surgical site during surgical procedures. However, Lightin Generator needs much lower output than PD #2 because Lightin Generator uses the LED light to indicate the small injection laryngoplasty site and the low output of Lightin Generator is technically sufficient for use.
Safety	IEC60601-1 IEC60601-1-2	IEC60601-1 IEC60601-1-2	**Same**
Reusable/Disposable	Reusable	Reusable	**Same**
Sterilization	N/A	N/A	**Same**

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9. Conclusion on SE based on Technical Comparison and Performance Data

The following performance testing has been performed for the proposed device;

Biocompatibility Testing

Lightin was accessed for conformity with the requirements of ISO 10993 series.

- ISO 10993-5: 2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (Recognition No: 2-245)
- ISO 10993-10: 2021 Biological evaluation of medical devices - Part 10: Tests for skin sensitization (Recognition No: 2-296)
- ISO 10993-23: 2021 Biological evaluation of medical devices - Part 23: Tests for irritation (Recognition No: 2-291)
- ISO 10993-11: 2017 Biological evaluation of medical devices - Part 11: Tests for systemic toxicity (Recognition No: 2-255)
- USP <151> Pyrogen Test (Recognition No:2-292)

Electrical Safety & EMC Testing

Lightin Generator was accessed for conformity with the requirements of IEC series.

- IEC 60601-1:2005/AMD2:2012 Edition 3.0 2012 MEDICAL ELECTRICAL EQUIPMENT – Part 1: General requirements for safety and essential performance. (Recognition No: 19-4)
- IEC 60601-1-2 Edition 4.0 2014-02 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests (Recognition No: 19-8)
- IEC TR 60601-4-2 Edition 1.0 2016-05 Medical electrical equipment - Part 4-2: Guidance and interpretation - Electromagnetic immunity: performance of medical electrical equipment and medical electrical systems (Recognition No: 19-19)

Non-Clinical Performance Testing

Lightin was accessed for conformity with the below requirements.

- ISO 80369-7: 2021 Small-bore connectors for liquids and gases in healthcare applications - Part 7: Connectors for intravascular or hypodermic applications (Recognition No: 5-133)
- ISO 80369-20: 2015 Small-bore connectors for liquids and gases in healthcare applications - Part 20: Common test methods (Recognition No: 5-97)

- ISO 7864: 2016 Sterile hypodermic needles for single use - Requirements and test methods (Recognition No : 6-379)
- ISO 9626: 2016 Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods(Recognition No: 6-380)
- ISO 11135: 2014 Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices [Including: Amendment 1 (2018)] (Recognition No: 14-529)
- ASTM F1980-16: Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices (Recognition No: 14-497)
- ASTM F1929-15: Standard Test Method for Detecting Seal Leaks in Porous Medical Packaging by Dye Penetration (Recognition NO: 14-484)
- ASTM F88 / F88M-15: Standard Test Method for Seal Strength of Flexible Barrier Materials (Recognition No: 14-482)
- USP <71> Sterility Test (Recognition No: 14-569)
- Internal test standard: light output test , Thermal measurement test
- ASTM D4169-22: Standard Practice Performance Testing of Shipping Containers and Systems (Recognition No: 14-576)

Performance Testing

Lightin System was accessed for conformity with the below requirements.

- The Lightin System successfully directs the laryngoplastic injection material to the target area within the vocal fold.
- The tissue heating concerns by the tip illumination.

Lightin and Lightin Generator was accessed for conformity with the below requirements.

- IEC 62471: 2006 Photobiological safety of lamps and lamp systems (Recognition No; 12-249)
- Internal Test Standard: Light Output Test

10. Conclusions

Based on a comparison of the various predicate devices and the reference device with the proposed Lightin System in terms of indication for use, technological characteristics, material and performance specifications, Lightin System raises no new issues of safety and effectiveness and is substantially equivalent to the predicate devices.