December 22, 2024

JiangXi Medex Technology Co.,Ltd
% Owen He
Consultant
Microkn Medical Technology Service (Shanghai) Co., Ltd.
Room 901,No.889, Pinglu Road, Jing'an District
Shanghai,
China

Re: K243121
Trade/Device Name: SLT Select Fiber Delivery System and Contact Tips (models SSRH 8-SMA; TCRH 7-SMA; FEF 2.2-SMA; CFE 0.6-SMA; SSRH 8Z-SMA; SSRH 4-SMA; SSRH 6-SMA; SSRH 9-SMA; SSRH 10-SMA; SSRH 11-SMA; SSRH 7L-SMA; TCRH 7Z-SMA; FEF 1.8-SMA; CFE 0.55-SMA; CFE 0.36-SMA; LAL 550-SMA; LAL 550Z-SMA; LAL 365-SMA; LAL 365Z-SMA; ER2; ERP2; GR2; GRP2; ER4; ERP4; GR4; GRP4; ER6; ERP6; GR6; GRP6; ER8; ERP8; GR8; GRP8; ER10; ERP10; GR10; GRP10; ER12; ERP12; GR12; GRP12; MD2.5; MD3.5; HP1.0; MTR1.5; MTR3.5; MTRG1.5; MTRG2.5; MTRG3.5; MT1.5; MT3.5; DF2; MTRGL3.5; MTRL6; MTRL7; MTRL8; MTRL10; R3ERP2; R4ERP2; D1ERP4; D3ERP4; D3GRP4; D3GRP10; D3GRP14; D3MTRG4; D3MTRG20; SERP4; SGRP4; SMD3.5; SMTRG3.5).

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: July 20, 2024
Received: September 30, 2024

Dear Owen He:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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,

YAN FU -S Digitally signed by YAN FU -S
Date: 2024.12.22 01:42:52 -05'00'

for Tanisha Hithe
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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K243121

Device Name
SLT Select Fiber Delivery System and Contact Tips (models SSRH 8-SMA; TCRH 7-SMA; FEF 2.2-SMA; CFE 0.6-SMA; SSRH 8Z-SMA; SSRH 4-SMA; SSRH 6-SMA; SSRH 9-SMA; SSRH 10-SMA; SSRH 11-SMA; SSRH 7L-SMA; TCRH 7Z-SMA; FEF 1.8-SMA; CFE 0.55-SMA; CFE 0.36-SMA; LAL 550-SMA; LAL 550Z-SMA; LAL 365-SMA; LAL 365Z-SMA; ER2; ERP2; GR2;

Indications for Use *(Describe)*
The SLT Select Fiber Delivery Systems and Contact Tips are intended to be used in general surgery as well as multiple surgical specialties such as Urology, Gynecology, ENT, Head and Neck, Gastroenterology, Neurosurgery, Thorasic surgery, Pulmonology, Plastic surgery and Orthopedics. The fiber delivery systems and tips achieve the precise tissue effects of incision, excision, vaporizationand coagulation of tissue. The universal SMA-905 connector allows this family of fiber delivery systems to be used with any laser system of 532 to 1064 nm wavelength which accepts the SMA-905connector.

·Laser must operate at a wavelength between 532 and 1064 nm.

* Laser must operate in Continuous Wave (CW) or Quasi Continuous Wave (Quasi CW) mode.

· Laser must have a numerical aperture of 0.35 or less.

· Laser must accept universal SMA-905 connector, SLT proprietary connector, or an appropriate adapter into its fiber launch connector.

Note: These Fiber Delivery Systems are cleared for use for the particular indications of the laser system to which they are connected.

During use these products are exposed to biohazardous substances such as blood and other bodily fluids. They should be disposed of per your facility's procedures for biohazardous waste.

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.

510(k) #: K243121

510(k) Summary

Prepared on: 2024-11-28

Contact Details

21 CFR 807.92(a)(1)

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Correspondent Address	Room 901,No.889, Pinglu Road, Jing'an District, Shanghai Shanghai China
Correspondent Contact Telephone	+86 13795451145
Correspondent Contact	Mr. Owen He
Correspondent Contact Email	fda@microkn.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	SLT Select Fiber Delivery System and Contact Tips (Models: SSRH 8-SMA; TCRH 7-SMA; FEF 2.2-SMA; CFE 0.6-SMA; SSRH 8Z-SMA; SSRH 4-SMA; SSRH 6-SMA; SSRH 9-SMA; SSRH 10-SMA; SSRH 11-SMA; SSRH 7L-SMA; TCRH 7Z-SMA; FEF 1.8-SMA; CFE 0.55-SMA; CFE 0.36-SMA; LAL 550-SMA; LAL 550Z-SMA; LAL 365-SMA; LAL 365Z-SMA; ER2; ERP2; GR2; GRP2; ER4; ERP4; GR4; GRP4; ER6; ERP6; GR6; GRP6; ER8; ERP8; GR8; GRP8; ER10; ERP10; GR10; GRP10; ER12; ERP12; GR12; GRP12; MD2.5; MD3.5; HP1.0; MTR1.5; MTR3.5; MTRG1.5; MTRG2.5; MTRG3.5; MT1.5; MT3.5; DF2; MTRGL3.5; MTRL6; MTRL7; MTRL8; MTRL10; R3ERP2; R4ERP2; D1ERP4; D3ERP4; D3GRP4; D3GRP10; D3GRP14; D3MTRG4; D3MTRG20; SERP4; SGRP4; SMD3.5; SMTRG3.5)
Common Name	Laser surgical instrument for use in general and plastic surgery and in dermatology
Classification Name	Powered Laser Surgical Instrument
Regulation Number	878.4810
Product Code(s)	GEX

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code

K980156	SLT SELECT FIBER DELIVERY SYSTEM AND CONTACT TIPS	GEX

Device Description Summary

21 CFR 807.92(a)(4)

The SLT select fiber delivery system and contact tips is the transmission path for 810nm, 980nm wavelength laser energy from the laser generator to the surgical site, with the optical fiber as the propagation medium, by transmitting the light energy to the diseased area, to achieve the treatment of the disease.

The SLT select fiber delivery system and contact tips, except for the CFE series and the LAL series of needle-tip one-piece flexible fibers, are fitted with a metal connector at the end (the metal connector is threaded to connect to the contact laser treatment head). The FEF series models can be used as non-contact lasers without a treatment head.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The SLT Select Fiber Delivery Systems and Contact Tips are intended to be used in general surgery as well as multiple surgical specialties such as Urology, Gynecology, ENT, Head and Neck, Gastroenterology, Neurosurgery, Thorasic surgery, Pulmonology, Plastic surgery and Orthopedics. The fiber delivery systems and tips achieve the precise tissue effects of incision, excision, vaporizationand coagulation of tissue. The universal SMA-905 connector allows this family of fiber delivery systems to be used with any laser system of 532 to 1064 nm wavelength which accepts the SMA-905connector.
·Laser must operate at a wavelength between 532 and 1064 nm.
* Laser must operate in Continuous Wave (CW) or Quasi Continuous Wave (Quasi CW) mode.
·Laser must have a numerical aperture of 0.35 or less.
· Laser must accept universal SMA-905 connector, SLT proprietary connector, or an appropriate adapter into its fiber launch connector.
Note: These Fiber Delivery Systems are cleared for use for the particular indications of the laser system to which they are connected. During use these products are exposed to biohazardous substances such as blood and other bodily fluids. They should be disposed of per your facility's procedures for biohazardous waste.

Indications for Use Comparison

21 CFR 807.92(a)(5)

The indication for use is the same with predicate devices.

Technological Comparison

21 CFR 807.92(a)(6)

The purposed device and the predicated device are same in product code, regulation number,the indications for use, Patient Population, Transmission efficiency, The tensile strength of the joint between the optical fiber transmission body and the connector, The optical fiber tensile strength, minimum bending working radius, optical fiber bending fatigue resistance, Divergence angle.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Non-clinical Testing
The bench testing of SLT Select Fiber Delivery Systems and Contact Tips and non-clinical testing is performed on new devices is to demonstrate the substantial equivalence to the predicate devices. Tests setup and execution are performed in accordance with applicable standards. Results of the testing demonstrate the compliance to the standards and matching the performance of new devices to the predicate devices. The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility test
In vitro cytotoxicity test, Skin sensitization, Intracutaneous reactivity, Pyrogen, Acute systemic toxicity were conducted according to ISO 10993-5:2009, ISO 10993-10:2021, ISO 10993-23:2021, ISO 10993-11:2017.

No clinical study is included in this submission.

The SL T Select Fiber Delivery Systems and Contact Tips are substantially equivalent to the predicate device.