January 24, 2020

LCCS Products Limited
Nick Xu
Regulatory Affairs
Office 3a-7, 12/F, Kaiser Center, No.18 Center Street, Sai Ying Pun
Hong Kong, China

Re: K191293
Trade/Device Name: LCCS VC-S RF Cannula
Regulation Number: 21 CFR 882.4725
Regulation Name: Radiofrequency Lesion Probe
Regulatory Class: Class II
Product Code: GXI
Dated: December 23, 2019
Received: December 26, 2019

Dear Nick Xu:

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,

Matthew Krueger, M.S.E.
Assistant Director
DHT5A: Division of Neurosurgical,
Neurointerventional
and Neurodiagnostic Devices
OHT5: Office of Neurological
and Physical Medicine Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration
06/30/2020

Form Approved: OMB No. 0910-0120
Expiration Date:

See PRA Statement below.

Indications for Use

510(k) Number (*if known*)

K191293

Device Name

LCCS VC-S RF Cannula

Indications for Use (*Describe*)

The LCCS VC-S RF Cannula is intended for use in RF heat lesion procedures for the relief of pain.

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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LCCS Products Limited
510(k) Premarket Notification Submission

510(k) Summary

In accordance with 21 CFR 807.92 the following summary of information is provided:

1. Date: February 28, 2019

2. Submitter: LCCS Products Limited

   Office 3a-7, 12/F, Kaiser Center, No.18 Center Street, Sai Ying Pun, Hong Kong

   Contact person: Nick XU
   Regulatory Affairs
   LCCS Products Limited
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3. Device Name:
   LCCS VC-S RF Cannula

Product Code	Classification	Regulation Section	Panel
GXI	Class II	21 CFR 882.4725 Probe, Radiofrequency Lesion	Neurology

4. Predicate Devices:

Predicate Device 510 (k) number	Predicate Device name
K112231	LCCS Insulated Spinal Needle (RF Cannula)
K123178	Stryker® Venom™ Electrodes and Cannulae

5. Device Description:

   The LCCS VC-S RF Cannula is used in conjunction with the RF electrode for the use in RF heat lesion procedures. The LCCS VC-S RF Cannulas are offered in a variety of lengths, gauges to accommodate various anatomical locations and differences in patients' anatomy. The LCCS VC-S RF Cannula is a stainless steel cannula with an insulated shaft having one exposed tip and one side port located at the end of the cannula to diffuse the anesthesia closer to the lesion site and deliver the RF energy to the tissue. When RF Electrode was inserted into LCCS VC-S RF Cannula and came out from the side port, both active tip and RF Electrode section stuck out of side port can deliver Radio Frequency energy. Please refer to Figure 5-1 RF energy outlet indicator diagram.

This RF cannula is provided as a sterile, single use, disposable device. This RF Cannula is offered in a variety of length and Needle outside Dimension to accommodate various anatomical locations and differences in patient anatomy.

Figure 5-1 RF energy outlet indicator diagram

The LCCS VC-S RF Cannula is consisted of:

a) Protection Sleeve
b) Needle Tube
c) Insulating layer
d) Needle hub
e) Stylet
f) Stylet Hub

6. Intended Use/Indications for Use:

The LCCS VC-S RF Cannula is intended for use in RF heat lesion procedures for the relief of pain.

7. Technology:

The LCCS VC-S RF Cannula employs the same fundamental scientific technology as its predicate devices.

LCCS VC-S RF Cannula is the same usage as its predicated devices, which is used in conjunction with RF denervation probes and RF Generator to create Radiofrequency (RF) Lesions of nerve tissue or for use in percutaneous nerve blocks.

Radiofrequency heat lesion procedure is a common technique used in the treatment of chronic pain. The LCCS VC-S RF Cannula and its predicate devices are offered in a variety of lengths, gauges to accommodate various anatomical locations and differences in patients' anatomy. The LCCS VC-S RF Cannula is a stainless steel cannula with an insulated shaft having one exposed tip and one side port located at the end of the cannula to diffuse the anesthesia closer to the lesion site and deliver the RF energy to the tissue. The tip and the side port constitute Y-shaped energy channels

and RF energy can be delivered both from these two channels.

8. Determination of Substantial Equivalence:

Comparison to Predicate Devices:

Below table is the summary comparison of features of the LCCS VC-S RF Cannula and the predicate devices.

Feature	**Proposed Device: LCCS VC-S RF Cannula**	**Predicate Device: LCCS Insulated Spinal Needle (RF Cannula) (K112231)**	**Predicate Device: Stryker® Venom™ Electrodes and Cannulae (K123178)**	**Discussion of Differences**
Intended/ Indications for use	The LCCS VC-S RF Cannula is intended for use in RF heat lesion procedures for the relief of pain.	LCCS Insulated Spinal Needle (RF Cannula) is indicated for use in RF heat lesion procedures for the relief of pain.	The Stryker RF electrodes and cannulae, in combination with the Stryker RF Generator/Multigen, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. These products are also used for selective denervation and tissue destruction procedures which may be performed on the lumbar, thoracic, and cervical regions of the peripheral nerves, and nerve roots for the relief of pain. Examples include, but are not limited to, Facette Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.	Identical
Material type	Stainless Steel	Stainless Steel	Stainless Steel	Identical
Needle Gauge	18G, 20G, 22G	18G, 20G, 22G	18G, 20G	Identical. The Needle Gauge of proposed device is identical to the predicate device: LCCS Insulated Spinal Needle (RF Cannula) (K112231)
Needle Tube Length	50mm, 100mm, 150mm	50mm, 100mm, 150mm	100mm, 150mm	Identical. The Needle Tube Length of proposed device is identical to the predicate device: LCCS Insulated Spinal Needle (RF Cannula) (K112231)

Feature	**Proposed Device: LCCS VC-S RF Cannula**	**Predicate Device: LCCS Insulated Spinal Needle (RF Cannula) (K112231)**	**Predicate Device: Stryker® Venom™ Electrodes and Cannulae (K123178)**	**Discussion of Differences**
Structure	A bevel tip and one side port locate at the distal end of the cannula. There are two channels to deliver the RF energy.	A bevel tip locates at the distal end of the cannula. There is no side port and only one channel to deliver the RF energy.	A bevel tip and a side port are created at the distal end of the cannula.	Identical. The proposed device is identical to the predicate device: Stryker® Venom™ Electrodes and Cannulae (K123178)
Method of Sterilization	Single use, Ethylene Oxide sterilization	Single use, Ethylene Oxide sterilization	Single use, Ethylene Oxide sterilization	Identical
Biocompatibility	Non-Cytotoxicity Non-Acute Systemic Toxicity Non-Intracutaneous Reactivity Non-Material Pyrogen Non- Skin Sensitization	Non-Cytotoxicity Non-Intracutaneous Reactivity Non- Skin Sensitization	Unknown	Equivalent. The subject device is also comply with ISO 10993-11:2012 with non-Material Pyrogen and non- Non-Acute Systemic Toxicity.

From the comparison summary table, the LCCS VC-S RF Cannula is substantially equivalent to the predicated devices with regard to intended use, technological characteristics, safety and effectiveness.

- The devices are all intended for used in conjunction with the RF denervation Probes for the use in RF heat lesion procedures.
- The devices are all offered in a variety of lengths, gauges to accommodate various anatomical locations and differences in patient anatomy.
- The proposed device and predicated devices are all have the same material of the needle, the needle of the devices are all made of stainless steel.
- The proposed device has the same structure of a bevel tip and a side port at the distal end of the cannula with its predicated device Stryker® Venom™ Electrodes and Cannulae (K123178). The proposed device and this predicated device both can provide two channels to deliver the RF energy.
- The devices are all offered with single use, and the methods of sterilization are all Ethylene Oxide sterilization.

9. Summary of Non-Clinical Tests:

LCCS VC-S RF Cannula has been evaluated for insulation inspection, biocompatibility, accelerated aging test as well as shelf life, sterilization, and mechanical safety, and has been found to conform to applicable medical device safety standards. The LCCS VC-S RF Cannula complies with below voluntary standards:

1. AAMI/ANSI ES 60601-2-2, Medical electrical equipment - Part 2-2: Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories
2. ISO 7864, Sterile hypodermic needles for single use - Requirements and test methods
3. ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
4. ANSI AAMI ISO 11607-1, Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
5. ANSI AAMI ISO 11135, Sterilization of health care products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.
6. ISO 14971, Medical devices - Applications of risk management to medical devices
7. ASTM F1980-16, Sterile hypodermic needles for single use - Requirements and test methods

The following quality assurance measures are applied to the development of the system:

- Risk Analysis
- Performance testing (Verification)
- Safety testing (Verification)

The LCCS VC-S RF Cannula is provided with sterilization and is biocompatible.

The Biocompatibility test details information as below:

Components	**Test**	**Results**	**Conclusions**
Needle tube, Stylet, Needle Hub	Cytotoxicity	The extract did not show potential toxicity to L-929 cells.	Non-Cytotoxic
	Acute Systemic Toxicity	The sample extracts showed no significant evidence of causing acute systemic toxicity in the mouse.	Non-Acute Systemic Toxicity
	Sensitization	The sample extract showed no significant evidence of causing skin sensitization in the guinea pig.	Non-Sensitization
	Intracutaneous Reactivity	The test result showed that the extract of the test article did not induce Intracutaneous reactivity in rabbit.	Non-Intracutaneous Reactivity
	Pyrogen	The animals' body temperature changed less than 0.5 degree C. The test article met the requirement of the absence of pyrogens.	Non- Pyrogen

10. Conclusion

LCCS Products Limited considers the LCCS VC-S RF Cannula to be as safe, as effective, and performance is substantially equivalent to the predicate devices.