September 7, 2022

Shenzhen Shineyard Medical Device Co. Ltd.
% Joyce Yang
Consultant
Shenzhen Joyantech Consulting Co., Ltd.
1713A, 17th Floor, Block A, Zhongguan Times Square
Nanshan District
Shenzhen, Guangdong 518100
China

Re: K220920
Trade/Device Name: Matreneu Percutaneous Balloon Compression Kit
Regulation Number: 21 CFR 882.4535
Regulation Name: Nonpowered Neurosurgical Instrument
Regulatory Class: Class I
Product Code: HAO
Dated: August 8, 2022
Received: August 8, 2022

Dear Joyce Yang:

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,

Adam Pierce, Ph.D.
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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K220920

Device Name
Matreneu Percutaneous Balloon Compression Kit

Indications for Use *(Describe)*
The Matreneu Percutaneous Balloon Compression Kit is intended to be used to the Percutaneous Balloon Compression (PBC) procedure for primary trigeminal neuralgia.

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

Date of Summary prepared: September 7, 2022

1. Submission Sponsor

Applicant Name	Shenzhen Shineyard Medical Device Co. Ltd.
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2. Submission correspondent

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Contact Person	Joyce Yang
Email	joyce@cefda.com

3. Device Identification

Type of 510(k) submission:	Traditional
Trade Name:	Matreneu® Percutaneous Balloon Compression Kit
Classification name:	Instrument, Surgical, Non-Powered
Review Panel:	Neurology
Product Code:	HAO
Device Class:	1
Regulation Number:	21 CFR § 882.4535

4. Legally Marketed Predicate Device

Trade Name	MULLAN GANGLION MICROCOMPRESSION SET
Regulation number	21 CFR § 882.4535
Regulation class	1
Regulation name	Nonpowered neurosurgical instrument
510(k) Number	K940973
Product Code	HAO
Manufacturer	COOK Incorporated

5. Device Description

The Matreneu® Percutaneous Balloon Compression Kit is intended to be used to the Percutaneous Balloon Compression (PBC) procedure for primary trigeminal neuralgia.

The subject device consist of five parts, such as the balloon catheter, puncture needle, syringe, connector, and pressure gauge. Through a sheath under X-ray fluoroscopy, a micro-balloon is introduced into the meniscus of the trigeminal nerve in Meckel's cavity to assist in retraction and establishment of a pathway. Then inject the contrast agent to fill the balloon to relieve the compression of the nerve fibers that cause trigeminal neuralgia. And through the expansion of the micro-balloon compression injury to treat trigeminal neuralgia.

The Kit is supplied sterile and is intended for single use.

6. Intended Use/ Indications for Use

The Matreneu® Percutaneous Balloon Compression Kit is intended to be used to the Percutaneous Balloon Compression (PBC) procedure for primary trigeminal neuralgia.

7. Technological characteristics comparison

Comparison item	Subject Device: Matreneu® Percutaneous Balloon Compression Kit	Predicate Device: MULLAN GANGLION MICROCOMPRESSION SET(K940973)	Comments
Product Code	HAO	HAO	Same
Regulation Number	21 CFR § 882.4535	21 CFR § 882.4535	Same
Classification	Class I	Class I	Same
Type of use	Prescription Use	Prescription Use	Same
Intended use & Indications for Use	The Matreneu Percutaneous Balloon Compression Kit is intended to be used to the Percutaneous Balloon Compression (PBC) procedure for primary trigeminal neuralgia.	The Mullan Percutaneous Trigeminal Ganglion Microcompression Set is intended for use in the percutaneous treatment of trigeminal neuralgia. This set is supplied sterile in a peel - open package and is intended for one - time use.	Same
Applicable user	The subject device is indicated for patients with trigeminal neuralgia treated by compression	The subject device is indicated for patients with trigeminal neuralgia treated by compression	Same

Comparison item	Subject Device: Matreneu® Percutaneous Balloon Compression Kit	Predicate Device: MULLAN GANGLION MICROCOMPRESSION SET(K940973)	Comments
	neurosurgery.	neurosurgery.	
Environment of use	The subject device expected to be used in a sterile operating room.	The subject device expected to be used in a sterile operating room.	Same
Single /repeat use	Single use	Single use	Same
Sterile /non-sterile	Marketed as a sterile device	Marketed as a sterile device	Same
Sterilization method and SAL	ETO sterile $SAL=10^{-6}$	ETO sterile $SAL=10^{-6}$	Same
Components	Balloon catheter Puncture needle Syringe Connector Pressure gauge	Microcompression Balloon Catheter Needle with stylet Syringe Scalpel Needle Angled needle gauge Gauze pad Adhesive bandage	Different (Issue 1)
Working principle	Through a sheath under X-ray fluoroscopy, a micro-balloon is introduced into the meniscus of the trigeminal nerve in Meckel's cavity to assist in retraction and establishment of a pathway. Then slowly inject the contrast agent to fill the balloon to relieve the compression of the nerve fibers that cause trigeminal neuralgia. And through the expansion of the micro-balloon compression injury, so as to treat trigeminal neuralgia.	Through a sheath under X-ray fluoroscopy, a micro-balloon is introduced into the meniscus of the trigeminal nerve in Meckel's cavity to assist in retraction and establishment of a pathway. Then slowly inject the contrast agent to fill the balloon to relieve the compression of the nerve fibers that cause trigeminal neuralgia. And through the expansion of the micro-balloon compression injury, so as to treat trigeminal neuralgia.	Same

Issue 1: The components of the subject device are not exactly the same as the predicate device. Compared with the predicate device, the subject device contains the same key components as the predicate device, such as Balloon Catheter, Puncture needle, and Syringe. The difference is that the predicate device contains some accessories, such as Scalpel, Angled needle gauge,

Gauze pad and Adhesive bandage. However, these accessories do not affect the intended use, performance and clinical operation of the device. In addition, the subject device includes connector and pressure gauge. The connector is used to connect the balloon catheter to the pressure gauge. The pressure gauge is only used to show the injection pressure, not to determine the amount of contrast agent to be injected. The connector and the pressure gauge also do not affect the intended use and performance of the device. Therefore, the differences dot not raise new risk of safety and effectiveness.

8. Summary of non-clinical testing

Performance testing was conducted on physical and chemical properties to support the marketing claims and to confirm that the safety and effectiveness of the Matreneu® Percutaneous Balloon Compression Kit is at least equivalent to the predicate device.

The EO residual was measured after sterilization of the device to meet the criteria defined in ISO 11135 Second edition 2014 and ISO 10993-7:2008.

The shelf-life for three years had been validated in real-time aging test and the requirements on packaging for terminally sterilized medical device per ISO 11607-1:2006 are also met. The testing successfully demonstrated essential performance is achieved before and after the shelf life test.

The biocompatibility evaluations were conducted in accordance with the 2020 FDA Guidance document Use of International Standard ISO-10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process". The cytotoxicity, sensitization, intracutaneous irritation, system toxicity, In Vitro Hemolytic Properties Test, and pyrogen tests were performed to demonstrate the biocompatibility of the device.

Tests on Electromagnetic Compatibility and Electrical Safety were performed in accordance to requirements per AAMI/ANSI ES 60601-1:2005/(R)2012 and A1:2012 and IEC 60601-1-2 Edition 3: 2007-03.

9. Brief discussion of clinical tests

No clinical tests were performed.

10. Conclusions

The conclusion drawn from the nonclinical tests demonstrates that the subject device, the Matreneu® Percutaneous Balloon Compression Kit are as safe and effective as the legally marketed predicate device cleared under K940973.