February 20, 2024

Shenzhen Leaflife Technology Co., Ltd
Qiang Cheng
Regulatory Affairs Manager
4F, Bldg. C, JMD Industrial Park, No.39 Qingfeng Blvd.,
Baolong Industrial Area, Longgang District
Shenzhen, Guangdong 518116, China

Re: K233760
Trade/Device Name: Mjolnir Pro. (Multi-electrode plasma)
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories
Regulatory Class: Class II
Product Code: QVJ
Dated: November 24, 2023
Received: November 24, 2023

Dear Qiang Cheng:

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,

Mark Trumbore -S

Digitally signed by Mark Trumbore -S
Date: 2024.02.20 11:14:11 -05'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K233760

Device Name
Mjolnir Pro. (Multi–electrode plasma)

Indications for Use *(Describe)*
Mjolnir Pro. With single-electrode plasma tip is used in the removal and destruction of skin lesions and coagulation of tissue.

Mjolnir Pro. With Multi–electrode plasma tip is intended for use in dermatologic and general surgical procedures for coagulation and hemostasis.

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.

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510(k) Summary

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

I. Contact Details

Shenzhen Leaflife Technology Co., Ltd

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Date Prepared:	5/2/2024

II. Proposed Device

Trade Name:	Mjolnir Pro. (Multi–electrode plasma)
Model(s):	LE-EPSMC
Common Name:	Low Power Electrosurgical Devices For Skin Lesion Destruction
Classification Name:	Electrosurgical cutting and coagulation device and accessories.
Regulation Number	878.4400
Regulation Class:	II
Product Code:	QVJ

III. Legally Marketed Predicate Device

Predicate device (Primary)	
510(k) Number:	K212329
Device Name:	Plasma IQ
Manufacturer:	Neauvia North America, Inc
Predicate device (1#)	
510(k) Number:	K201738
Device Name:	SubNovii Advanced Plasma Technology
Manufacturer:	Cartessa Aesthetics
Predicate device (2#)	
510(k) Number:	K201520
Device Name:	The Alma Opus System, Colibri Applicator and Tips
Manufacturer:	Alma Lasers Inc.

The predicates have not been subject to a design-related recall.

IV. DEVICE DESCRIPTION SUMMARY

Mjolnir Pro. With single-electrode plasma tip is used in the removal and destruction of skin lesions and coagulation of tissue. With Multi–electrode plasma tip is intended for use in dermatologic and general surgical procedures for coagulation and hemostasis. Under the controllable way, the device utilizes a treatment method called plasma sublimation, which causes controlled skin damage through the generation of an electrical arc. The arc between the electrode tip and the skin is created by a radio frequency generator housed in an electrosurgical unit (handpiece) that ionizes the gas

particles in the air. A straight active electrode made of 316 stainless steel is available with the system.

V. Indications for use

Mjolnir Pro. With single-electrode plasma tip is used in the removal and destruction of skin lesions and coagulation of tissue.

Mjolnir Pro. With Multi–electrode plasma tip is intended for use in dermatologic and general surgical procedures for coagulation and hemostasis.

VI. Comparison of Indications for Use and Technological Characteristics

The Mjolnir Pro. (Multi–electrode plasma) is the same or similar to the cleared predicate devices.

The Mjolnir Pro. (Multi–electrode plasma) has the same intended use, and similar technological characteristics. Please refer to the following table for details:

Item	Proposed Device K233760	Predicate Device K212329 (Primary)	Predicate Device (1#) K201738	Predicate Device (2#) K201520	Remark
Device name	Mjolnir Pro (Multi–electrode plasma)	Plasma IQ	SubNovii Advanced Plasma Technology	The Alma Opus System, Colibri Applicator and Tips	/
Product model	LE-EPSMC	/	ZHFIPL-II, ZHF-IPL-III	LM-LNIRA, LM-LNIRB	/
K number	K233760	K212329	K201738	K201520	/
Product code	QVJ	GEI	GEI	GEI	Same
Classification regulation	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	21 CFR 878.4400	Same
Indications for use	Mjolnir Pro. With single-electrode plasma tip is used in the removal and destruction of skin lesions and coagulation of tissue. Mjolnir Pro. With Multi–electrode plasma tip is intended for use in dermatologic and general surgical procedures for coagulation and hemostasis.	PLASMA IQ is used in the removal and destruction of skin lesions and coagulation of tissue.	Intended for the removal and destruction of skin lesions and coagulation of tissue.	The Opus Plasma Tips (Focus and Glide), when used with the unipolar applicator, are indicated for dermatological procedures requiring ablation and resurfacing of the skin.	Same
Prescription use or not	Prescription use	Prescription use	Prescription use	Prescription use	Same

Item	Proposed Device K233760	Predicate Device K212329 (Primary)	Predicate Device (1#) K201738	Predicate Device (2#) K201520	Remark
Mode of operation	Plasma	Plasma	Plasma	Plasma	Same
Handle mode	Multi–electrode plasma handle: • Single–electrode plasma tip • Multi–electrode plasma tip ○ Dot matrix shape settings: 3dots, 5dots, 9dots,13dots, 21dots, 25dots. Low power plasma handle, Single tip.	Single tip	Single tip	Glide (Roller): • Roller Rows: 6 • Diameter: 12mm • Distance between pixels: 1mm • Width: 10mm • Focus:IN and Focus: • Diameter: 12mm • Distance between pixels: 1mm	Similar
Power supply	110–230Va.c. 50/60Hz	110 – 250Va.c. 50/60 Hz	110-250Va.c. 50/60 Hz	120VAC, 50/60Hz	Similar
Frequency	40/82KHz	40KHz	40KHz	40.68MHz	Similar
Max output power	5W	5W	5W	5-100W	Same

Discussion

As we can see from the table above, the proposed device and the predicate device differ slightly in terms of power supply, frequency, and system components, and this difference can be demonstrated in non-clinical trials to have no safety implications.

In addition, there are some differences in the output modes of the handle treatment heads, the main Predicate Device K212329 and K201738 have only one spot output mode (Single tip). Whereas the Proposed device has multiple disperse electrode modes in addition to one spot output mode. The source of energy is still the same as one spot, but at the end of the output, it is designed as a matrix mode, which can be overridden by the Glide (Roller) mode in the Predicate Device K201520, which belongs to the Roller mode, which is also a dot matrix output mode.

The power supply range of the proposed device is within the coverage of the predicate device. Through performance testing, it can be determined that the range of thermal damage to ex vivo animal tissue from the plasma output of the proposed device is the same as that of the Predicate Device. Therefore, these differences in frequency between the proposed device and the Predicate Device do not affect the safety and effectiveness of the device.

Item	Proposed Device	Predicate Device K212329 (Primary)	Predicate Device K201738	Predicate Device K201520	Remark
Cytotoxicity	No Cytotoxicity	No Cytotoxicity	No Cytotoxicity	/	Same
Sensitization	No evidence of sensitization	No evidence of sensitization	No evidence of sensitization	/	Same
Irritation	No evidence of irritation	No evidence of irritation	No evidence of irritation	/	Same
Electrical Safety	Comply with ANSI/AAMI ES60601-1	Comply with ANSI/AAMI ES60601-1, IEC 60601-2-2	Comply with ANSI/AAMI ES60601-1, IEC 60601-2-2	Comply with ANSI/AAMI ES60601-1, IEC 60601-2-2	Same
EMC	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Comply with IEC 60601-1-2	Same

VII. Non-Clinical Test Conclusion

Non-clinical tests were conducted to verify that the proposed device met all design specifications as was Substantially Equivalent (SE) to the predicate devices. The test results demonstrated that the proposed device complies with the following standards:

ANSI/AAMI ES60601-1:2005/(R) 2012 and A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, Medical electrical equipment — Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2:2014, Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests.

IEC 60601-2-2:2017, 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.

ISO 10993-5 Third Edition 2009-06, Biological Evaluation of Medical Devices - Part 5: Tests For In Vitro Cytotoxicity. (Biocompatibility)

ISO 10993-10 Third Edition 2021-11, Biological Evaluation of Medical Devices - Part 10: Tests for Skin Sensitization. (Biocompatibility)

ISO 10993-23 first Edition 2021-01, Biological Evaluation of Medical Devices - Part 23: Tests for irritation. (Biocompatibility)

Performance Testing for Tissue Thermal Effect Test Report. The tests were conducted on freshly ex vivo pig tissue. Histological evaluation with Hematoxylin-Eosin (H&E) demonstrated the tissue damages by the subject device are less than 0.25mm, which is considered superficial and substantially equivalent to the tissue damages.

Performance and safety tests that demonstrate that the device meets the requirements of the design inputs, including: accuracy of power output, and intended device functionality.

Software Verification and Validation Testing was conducted per “Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices”, and the level of concern was determined to be Moderate for the proposed device.

VIII. Conclusions

This comparison of the specifications demonstrates the functional equivalence of the devices. Shenzhen Leaflife Technology Co., Ltd. believes that the Mjolnir Pro. (Multi–electrode plasma) is as safe and effective and performs in a substantially equivalent manner to the predicates.