February 28, 2023

Mima-Pro Scientific Inc.
℅ Prithul Bom
Most responsible person
Regulatory Technology Services, LLC
1000 Westgate Drive,
Suite 510k
Saint Paul, Minnesota 55114

Re: K223272
Trade/Device Name: SurBlate Ablation System
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: NEY
Dated: October 21, 2022
Received: October 24, 2022

Dear Prithul Bom:

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,

Mark Trumbore -S
Digitally signed by Mark Trumbore -S
Date: 2023.02.28 07:58:23 -05'00'

On behalf of
Long Chen, Ph.D.
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K223272

Device Name
SurBlate™ Ablation System

Indications for Use *(Describe)*
The SurBlate™ Ablation System is intended for coagulation (thermoablation) of soft tissues. Not for use in cardiac procedures.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K223272

510(k) Summary

This summary of 510(k) is submitted in accordance with the requirements of 21 CFR §807.92:

I. SUBMITTER

Company Name: Mima-Pro (Nan Tong) Scientific Inc.
Address: Tongzhou District, 226300 Nantong City, Jiangsu Province, PRC
Contact Person: Jim Elliott
CEO - MIMA-PRO SCIENTIFIC INC.
Telephone: 604-209-0443
Facsimile: 604-279-6367
E-mail: jimelliott@mima-pro.ca
Date Prepared: 02-27-2023

II. DEVICE

Device Trade Name: SurBlate™ Ablation System
Device Model Number: SurBlate™-GEN model identified as MTC-3C
Classification Name: Electrosurgical Cutting and Coagulation Device and Accessories
Regulation: 21 CFR §878.4400
Regulatory Class: Class II
Product Classification Code: NEY
510k Review Panel: General and Plastic Surgery

III. PREDICATE DEVICE

Predicate Manufacturer: H.S. Hospital Service S.p.A.
Predicate Trade Name: HS AMICA
Predicate 510(k): K083157
This predicate has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

The SurBlate™ Ablation System is an integrated system for interstitial thermoablation of soft tissues through controlled emission of microwaves. The system is composed by four interactive devices (and one optional device), namely:

a) SurBlate™-GEN: a digitally controlled microwave power source, operating at 2450 MHz, and delivering up to 100 Watts CW (continuous wave). SurBlate™-GEN features a single output channel.

b) SurBlate™-APPLICATOR: an interstitial single-use coaxial microwave applicator, activated by the SurBlate™-GEN and connected to SurBlate™-GEN via the SurBlate™-COAX.

c) SurBlate™-PUMP: a peristaltic pump for convective applicator cooling through continuous circulation of liquid coolant, fully controlled by and attached to SurBlate™-GEN.

d) SurBlate™-COAX: a microwave coaxial cable serving as a medical grade microwave transmission line used for transmitting microwave energy. Its characteristic impedance is 50 ohm. In the system, it is used to transmit microwave energy from SurBlate™-GEN to the SurBlate™-APPLICATOR.

e) SurBlate™-FOOT (Optional): a foot pedal supplied with SurBlate™-GEN for remote control of energy delivery activation.

V. TECHNOLOGY CHARACTERISTICS

1. Output power of microwave source: Under rated grid voltage, microwave output power of microwave source machine is within the range of 0 Watts to 100 Watts, gradually adjusted in steps of 5 Watts with a deviation from set power of ±20%.
2. Operating time of microwave source: From 0 minutes to 1 minute the operating time of the microwave output power of the microwave source can be adjusted in steps of 1 second. From 1 minute to 15 minutes the operating time of microwave output power of the microwave source can be gradually adjusted in steps of 1 minute with a deviation of set time of ±1%.
3. VSWR (Voltage Standing Wave Ratio): The maximum VSWR for SurBlate™ under service conditions is ≤3.
4. Temperature range in the microwave ablation service area: Temperature range: 40°C - 112°C, error ±3°C.
5. Microwave output mode: Microwave output is continuous wave mode.
6. The SurBlate™-APPLICATOR have various lengths and diameters:

Model Number	Diameter (G)	Applicator Length (mm)
MP14150T16	14	150
MP14200T16	14	200
MP14270T16	14	270
MP16100T16	16	100
MP16150T16	16	150
MP16200T16	16	200
MP18100T16	18	100
MP18150T16	18	150
MP18200T16	18	200

7. Appearance and structure of machine: Surface of machine and accessories shall be color even, smooth, clean, no burrs, and coating without dropping off and scratch etc. Words, symbols and markings shall be accurate and clear. Switches and push buttons of machine shall be reliably secure to prevent operational failure.

VI. INDICATIONS FOR USE

The SurBlate™ Ablation System is intended for coagulation (thermoablation) of soft tissues. Not for use in cardiac procedures.

VII. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

The following characteristics were compared and shown to be the same between SurBlate™ Ablation Systems (SurBlate™) and the predicate device (HS AMICA) in order to demonstrate substantial equivalence:

a) Intended Use
b) Indications/Contra-indications
c) Operation Mechanism
d) Components
e) Applications Sites
f) Performance Specifications

g) Cooling System
h) Materials of Applicator/ Probe
i) Sterilization Method of Probe
j) Biocompatibility
k) Pump

In addition, the following characteristics were compared and shown to be the similar between SurBlate™ and HS AMICA in order to demonstrate substantial equivalence:

a) Technology Characteristic
b) Coagulative Performance
c) Performance Testing
d) Applicator/ Probe
e) Dimensions of Applicator/ Probe
f) A comparison between Surblate™ and HS AMICA device maximum output power and probe dimensions are as follows:

Feature/Specification	**SurBlate™**	**HS AMICA**
Maximum Output Power	100 Watts	100 Watts
Applicator Shaft Length	100 mm, 150 mm, 200 mm; 270 mm	150 mm, 200 mm, 270 mm
Applicator Diameter (Gauge (G))	14 G, 16G, 18G	11 G, 14 G, 16G

By definition, a device is substantially equivalent to a predicate device when the device has the same intended use and the same technological characteristics as the previously cleared predicate device, or has the same intended use and if there are different technological characteristics, and it can be demonstrated that the device is as safe and effective as the predicate device, and that the new device does not raise different questions regarding its safety and effectiveness as compared to the predicate device. It has been shown in this 510(k) submission that the slight differences between the SurBlate™ Ablation System and the predicate device do not raise any questions regarding its safety and effectiveness. SurBlate™ Ablation System, as designed and manufactured, is as safe and effective as the predicate device and therefore is determined to be substantially equivalent to the referenced predicate device. The SurBlate™ Ablation System is substantially equivalent in function and intended use to the following legally marketed device: HS AMICA (K083157) The SurBlate™ Ablation System operates at the same microwave frequency (2450 MHz) as HS AMICA and both systems achieve the thermoablation of selected soft tissues located inside the human body through the local delivery of microwave energy. Both systems are composed by a microwave generator, a single use interstitial applicator - capable of penetrating into tissues and delivering microwave energy to target tissues through its active distal tip - and by a peristaltic pump for continuous water circulation inside the applicator - for applicator cooling. Both systems allow the operator to select the microwave output power level and the procedure time, as required by the specific application. In both systems the microwave power output is started manually by the operator and may either be stopped manually at any time by the operator, or deactivated automatically when the selected procedure time has elapsed. Both systems exhibit software-based electronic control for operator ease of use in setting, handling and monitoring of the ablation procedure. Both systems possess a variety of software and hardware alarms and protections to prevent excessive energy delivery to tissues, overheating of the applicator's insertion track and other possible criticalities. The two systems, have similar overall coagulative performance and in the applicator and microwave source design, structure and architecture.

VIII. PERFORMANCE TESTING

The SurBlate™ Ablation System has been designed to comply with the applicable portions of various International Standards, including:

- IEC 60601-1:2012 (Reprint) + A1:2012 - Medical electrical equipment - Part 1: General requirements for basic safety and essential performance;
- IEC 60601-2-6:2012 (Second Edition) for use in conjunction with IEC 60601-1:2005 (Third Edition) + A1:2012 - Medical electrical equipment - Part 2: Particular requirements for the basic safety and essential performance of microwave therapy equipment;
- IEC 60601-1-2:2014 (Fourth Edition) + IEC 60601-2-6:2012 (Clause 202) - Medical Electrical Equipment - Part 1-2 General Requirements to Basic Safety and Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements and Tests;
- IEC 60601-1-2:2014 + A1:2020 (Only immunity tests) - Medical Electrical Equipment - Part 1-2 General Requirements to Basic Safety and Essential Performance Collateral Standard: Electromagnetic Disturbances Requirements and Tests;
- ISO 9626 Second Edition 2016, Stainless steel needle tubing for the manufacture of medical devices - Requirements and test methods;
- IEC 62366-1:2015 Medical devices – Part 1: Application of usability engineering to medical devices; and
- ASTM D4169-22 Standard Practice for Performance of Shipping Containers and Systems.

The following performance testing were undertaken to generate data in support of the substantial equivalence determination:

• Software verification and validation testing;
• Electrical safety and electromagnetic compatibility (EMC) testing;
• Performance testing - Bench (testing including: appearance of generator; output power; operating time; voltage standing wave ratio; temperature monitoring, microwave output mode, usability engineering, environmental operating and storage conditions; and transportation conditions).

The SurBlate™ Ablation System and the predicate device are substantially equivalent in design concepts, technologies and materials. The SurBlate™ Ablation System has been verified through rigorous testing that, in part, supports the compliance of SurBlate™ Ablation System to the standards listed above. The system passed all pre-determined acceptance criteria identified in the test plan. Ex-vivo testing in liver, kidney and muscle was conducted to produce data for the Operating Instructions for SurBlate™ Ablation System. The ex-vivo tissue ablation performance testing was conducted in simulated realistic, best case and worst-case scenarios. Ablation zones across tissue types and environments demonstrated safe and effective procedural success. In comparison to the predicate device, tissue type (porcine liver, kidney and muscle) was tested in the worst-case scenario (room temperature: 20 degrees C). The rational for testing in the worst-case scenario was to illustrate similar safe and effective coagulation (thermoablation) for both the subject and predicate device, with the clear understanding that the realistic and best-case scenarios would result in slightly greater ablation zones performance. Ex-vivo ablation sizes for the SurBlate™ Ablation System were deemed to be substantially equivalent to the predicate device. The method of measuring ablation zones is determined by measuring the sample processed with the triphenyltetrazolium chloride (TTC) dye technique. The non-stained area is the coagulated area, and the pink-colored area is the uncoagulated area. Verification and validation testing were completed in accordance with the company's Design Control process in compliance with 21 CFR Part 820.30, which included testing that fulfills the requirements of FDA "Guidance on Software Contained in Medical Devices". Potential risks were analyzed and satisfactorily mitigated in the device design.

IX. BIOCOMPATIBILITY TESTING

The biocompatibility evaluation for this device was conducted in accordance with:
a) Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process" - Guidance for Industry and Food and Drug Administration Staff - Issued September 4, 2020;
b) ISO 10993-1 Fifth Edition 2018-08, Biological Evaluation of Medical Devices - Part 1: Evaluation and testing within a risk management process;
c) ISO 10993-4: 2017: Biological Evaluation of Medical Devices, Part 4: Selection of tests for interaction with blood;
d) ISO 10993-5 Third edition 2009-06-01: Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity;
e) ISO 10993-10 Third Edition 2010-08-01: Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization;
f) ISO 10993-11:2017: Biological evaluation of medical devices Part 11: Tests for systemic toxicity;

X. STERILIZATION AND SHELF-LIFE

The sterilization and shelf-life for this device was conducted in accordance with ISO 11135-1:2014: Sterilization of healthcare products - Ethylene oxide - Requirements for development, validation and routine control of a sterilization process for medical devices.

Animal Study and Human Clinical performance testing were not required to demonstrate safety and effectiveness of SurBlate™ Ablation System.

XI. CONCLUSION

The SurBlate™ Ablation System has the same or similar intended use, indications for use, technological characteristics, and principles of operation as those of the predicate device. The minor differences between the SurBlate™ Ablation System and its predicate device raise no new issues of safety or effectiveness. Thus, the nonclinical tests demonstrated that the SurBlate™ Ablation System is as safe, as effective, and performs as well as or better than the predicate device.