November 27, 2023

Medinux (Tianjin) Technologies Co., Ltd.
Ms. Diana Zhang, B.A.
Manager, Regulatory Affairs
Room 401, Unit 3, Building K1
6 Haitai Fazhan 6th Road, Huayuan Industrial Park
Tianjin 300384
China

Re: K231661
Trade/Device Name: CryoThin™ Surgical System and Accessories
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: Class II
Product Code: GEH
Dated: November 3, 2023
Received: November 3, 2023

Dear Ms. Zhang:

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: 2023.11.27 10:22:03 -05'00'

Mark Trumbore, 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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K231661

Device Name
CryoThin™ Surgical System and Accessories

Indications for Use *(Describe)*
The CryoThin Surgical System is intended for cryosurgery in the fields of general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The system has the following specific indications:

General Surgery
• Destruction of warts or lesions
• Palliation of tumors of the oral cavity, rectum and skin
• Ablation of breast fibroadenomas
• Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions

Urology
• Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Gynecology
• Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology
• Ablation of cancerous or malignant tissue
• Ablation of benign tumors
• Palliative intervention

Neurology
• Freezing of nerve tissue in pain management/cryoanalgesia

Dermatology
• Ablation or freezing of skin cancers and other cutaneous disorders

Proctology
• Ablation of benign or malignant growths of the anus or rectum
• Ablation of hemorrhoids

Thoracic Surgery
• Ablation of cancerous lesions

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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K231661 510(k) SUMMARY

CryoThin™ Surgical System and Accessories

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

Submitter:	Medinux (Tianjin) Technologies Co., Ltd. Room 401, Unit 3, Building K1 6 Haitai Fazhan 6th Road Huayuan Industrial Park Tianjin 300384 China
Company Contact Person:	Ms. Diana Zhang, B.A. Manager, Regulatory Affairs Phone: (86) 22 86 392 536 Fax: (86) 22 87 930 633 dianazhang@medinux.com

Trade/Device Name:	CryoThin™ Surgical System and Accessories
Manufacturer:	Medinux (Tianjin) Technologies Co., Ltd.
Regulation Number:	21 CFR 878.4350
Regulation Name:	Cryosurgical unit and accessories
Regulation Class:	Class II
Product Code:	GEH
Predicate Devices / Reference 510(k):	CRYOCARE TOUCH System and Accessories (K201588) Visual-ICE® Cryoablation System (K143564)
Date of Preparation:	November 23, 2023

Device Description:

Cryosurgery is the use of ultra-low temperatures for selectively freezing and destroying diseased tissues in situ. The CryoThin™ Surgical System is designed to ablate benign and malignant tissues using cryosurgery.

The system utilizes the Joule-Thomson effect for freezing. It uses high-pressure argon gas that undergoes throttling expansion to induce freezing inside the closed tip of the Cryo probe to freeze the target tissue around the probe tip. Low-pressure argon is electrically heated and blown into the probe tip to thaw the tissue around it.

The CryoThin Surgical System consists of a console, a cart, and accessories. The system must be used in conjunction with the Cryo probes for freeze and thaw functions, and the Temp probes for monitoring the temperature in target or adjacent tissues.

Indications for Use:

The CryoThin Surgical System is intended for cryosurgery in the fields of general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The system has the following specific indications:

General Surgery

- Destruction of warts or lesions
- Palliation of tumors of the oral cavity, rectum and skin
- Ablation of breast fibroadenomas
- Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions

Urology

- Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia

Gynecology

- Ablation of malignant neoplasia or benign dysplasia of the female genitalia

Oncology

- Ablation of cancerous or malignant tissue
- Ablation of benign tumors
- Palliative intervention

Neurology

- Freezing of nerve tissue in pain management/cryoanalgesia

Dermatology

- Ablation or freezing of skin cancers and other cutaneous disorders

Proctology

- Ablation of benign or malignant growths of the anus or rectum
- Ablation of hemorrhoids

Thoracic Surgery

- Ablation of cancerous lesions

Technological Comparison:

Table 1 below provides a comparison of the technological characteristics of the subject device with the predicate devices.

Table 1 Subject and Predicate Device Comparison

Feature	Subject Device CryoThin Surgical System and Accessories	Predicate Device 1 CRYOCARE TOUCH System and Accessories	Predicate Device 2 Visual-ICE Cryoablation System	Comparison
510(k) Number	-	K201588	K143564	-
Trade/Device Name	CryoThin Surgical System and Accessories	CRYOCARE TOUCH System and Accessories	Visual-ICE Cryoablation System	-
Manufacturer	Medinux (Tianjin) Technologies Co., Ltd.	Varian Medical Systems, Inc.	Galil Medical Inc.	Same
Regulation Number	21 CFR 878.4350	21 CFR 878.4350	21 CFR 878.4350	Same
Regulation Name	Cryosurgical unit and accessories	Cryosurgical unit and accessories	Cryosurgical unit and accessories	Same
Regulation Class	Class II	Class II	Class II	Same
Product Code	GEH	GEH	GEH	Same
Indications for Use	The CryoThin Surgical System is intended for cryosurgery in the fields of general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the application of extreme cold temperatures including	The CRYOCARE TOUCH System is intended for use in open, minimally invasive, or endoscopic surgical procedures in the areas in general surgery, urology, gynecology, oncology, neurology, dermatology, ENT, proctology, pulmonary surgery and thoracic surgery. The system is designed to freeze/ablate tissue by the	The Visual-ICE Cryoablation System is intended for cryoablative destruction of tissue during surgical procedures. The Visual-ICE System is indicated for use as a cryosurgical tool in the fields of general surgery, dermatology, neurology (including cryoanalgesia), thoracic surgery, ENT, gynecology, oncology,	Same

Feature	Subject Device CryoThin Surgical System and Accessories	Predicate Device 1 CRYOCARE TOUCH System and Accessories	Predicate Device 2 Visual-ICE Cryoablation System	Comparison
	prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The system has the following specific indications: **General Surgery** • Destruction of warts or lesions • Palliation of tumors of the oral cavity, rectum and skin • Ablation of breast fibroadenomas • Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal	application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. In addition, the system is intended for use in the following indications: **General Surgery** • Destruction of warts or lesions • Palliation of tumors of the oral cavity, rectum and skin • Ablation of breast fibroadenomas • Ablation of leukoplakia of the mouth, angiomas, sebaceous hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, hemorrhoids, anal fissures, perianal condylomata, pilonidal	proctology, and urology. This system is designed to destroy tissue by the application of extreme cold temperatures including prostate and kidney tissue, liver metastases, tumors, skin lesions, and warts. The Visual-ICE Cryoablation System has the following specific indications: • **Urology:** Ablation of prostate tissue in cases of prostate cancer and Benign Prostate Hyperplasia (BPH) • **Oncology:** Ablation of cancerous or malignant tissue and benign tumors, and palliative intervention • **Dermatology:** Ablation or freezing of skin cancers and other cutaneous disorders Destruction of warts or lesions, angiomas, sebaceous	

Feature	Subject Device CryoThin Surgical System and Accessories	Predicate Device 1 CRYOCARE TOUCH System and Accessories	Predicate Device 2 Visual-ICE Cryoablation System	Comparison
	cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions **Urology** • Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia **Gynecology** • Ablation of malignant neoplasia or benign dysplasia of the female genitalia **Oncology** • Ablation of cancerous or malignant tissue • Ablation of benign tumors • Palliative intervention **Neurology** • Freezing of nerve tissue in pain management/cryoanalgesia **Dermatology** • Ablation or freezing of skin cancers and other cutaneous	cysts, actinic and seborrheic keratoses, cavernous hemangiomas, recurrent cancerous lesions **Urology** • Ablation of prostate tissue in cases of prostate cancer and benign prostatic hyperplasia **Gynecology** • Ablation of malignant neoplasia or benign dysplasia of the female genitalia **Oncology** • Ablation of cancerous or malignant tissue • Ablation of benign tumors • Palliative intervention **Neurology** • Freezing of nerve tissue in pain management/cryoanalgesia **Dermatology** • Ablation or freezing of skin cancers and other cutaneous	hyperplasia, basal cell tumors of the eyelid or canthus area, ulcerated basal cell tumors, dermatofibromas, small hemangiomas, mucocele cysts, multiple warts, plantar warts, actinic and seborrheic keratosis, cavernous hemangiomas, peri-anal condylomata, and palliation of tumors of the skin. • **Gynecology:** Ablation of malignant neoplasia or benign dysplasia of the female genitalia • **General surgery:** Palliation of tumors of the rectum, hemorrhoids, anal fissures, pilonidal cysts, and recurrent cancerous lesions, ablation of breast fibroadenomas • **ENT:** Palliation of tumors of the oral cavity and ablation of leukoplakia of the mouth • **Thoracic surgery:** Ablation of arrhythmic cardiac tissue	

Feature	Subject Device CryoThin Surgical System and Accessories	Predicate Device 1 CRYOCARE TOUCH System and Accessories	Predicate Device 2 Visual-ICE Cryoablation System	Comparison
	disorders **Proctology** • Ablation of benign or malignant growths of the anus or rectum • Ablation of hemorrhoids **Thoracic Surgery** • Ablation of cancerous lesions	disorders **Proctology** • Ablation of benign or malignant growths of the anus or rectum • Ablation of hemorrhoids **Thoracic Surgery** • Ablation of cancerous lesions	cancerous lesions • **Proctology:** Ablation of benign or malignant growths of the anus or rectum, and hemorrhoids	
Mechanism of action	Joule-Thomson effect	Joule-Thomson effect	Joule-Thomson effect	Same
Freeze gas	Argon gas	Argon gas	Argon gas	Same
Thaw gas	Argon gas	Helium gas	Helium gas Argon gas	Same as Predicate Device 2
Electrical Thaw	Yes (electrical heated argon gas)	N/A	Yes (electrical heated argon gas)	Same as Predicate Device 2
Human interface device / connections	● 1×touch screen monitor	● 1×touch screen monitor ● 1×Remote Keypad	● 1×touch screen monitor	Same as Predicate Device 2

Summary of Performance Data (Non-clinical testing):

The CryoThin Surgical System and Accessories have the same principle of operation, intended use, and very similar technological characteristics as the predicate devices.

Comprehensive tests and analysis have been performed on the subject device which demonstrated the safety and performance characteristics of the device. The non-clinical testing done on the subject device include the following:

a. Electrical Safety Testing in accordance with IEC 60601-1.
b. Electromagnetic Compatibility Testing in accordance with IEC 60601-1-2.
c. Human Factors and Usability Testing in accordance with IEC 60601-1-6 and IEC 62366.
d. Software development in accordance with IEC 62304 and the FDA's Guidance, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices."
e. Biocompatibility Testing in accordance with ISO 10993 series of standards.
f. Sterilization Validation in accordance with ISO 11137-1, ISO 11137-2, 11137-3, ISO 11737-1, and ISO 11737-2.
g. Shelf-life testing in accordance with ASTM F 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.
h. Service life testing in accordance with IEC 62506:2013 Methods for Product Accelerated Testing.
i. Package Verification Testing in accordance with ASTM F 1980-16 Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices
j. Packaging Testing in accordance with ASTM D 4169-16 Standard Practice for Performance Testing of Shipping Containers and Systems DC13 Level II.
k. Cleaning and Disinfection of Reusable Probes testing to support the stated use life.
l. Iceball and isotherm testing to demonstrate the subject device ability to cool target tissue to desirable therapeutic temperature.
m. Compatibility testing to demonstrate subject device compatibility with the most commonly used imaging modalities.

Conclusion:

The subject device has passed all the above testing. The testing results showed its conformance to applicable requirements specifications and assured that the safety measures taken are adequate and effective. The information and data provided in this Traditional 510(k) application demonstrated that the subject device met the safety and performance specifications and did not raise any new safety or effectiveness issues. Thus, the subject device is considered to be substantially equivalent to the legally marketed predicate devices.