



October 4, 2024

Surgnova Healthcare Technologies (Zhejiang) Co., Ltd.  
Guofang Ma  
QARA Director  
No.1 XinXing Yilu Road, Emerging Industrial Cluster Area  
Zonghan Subdistrict  
Cixi, Zhejiang 315301  
China

Re: K240376

Trade/Device Name: Electroporation System (N3000)

Regulation Number: 21 CFR 878.4400

Regulation Name: Electrosurgical Cutting And Coagulation Device And Accessories

Regulatory Class: Class II

Product Code: OAB

Dated: February 6, 2024

Received: September 4, 2024

Dear Guofang Ma:

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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at <https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system>.

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](mailto:DICE@fda.hhs.gov)) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

**Long H. Chen**  Digitally signed by Long H. Chen -S  
Date: 2024.10.04 13:21:09 -04'00'

Long Chen, Ph.D.  
Assistant Director  
DHT4A: Division of General Surgery Devices  
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Enclosure

## Indications for Use

510(k) Number (if known)  
K240376

Device Name  
Dophi Electroporation System (N3000)

Indications for Use (Describe)

The Dophi Electroporation System is intended for surgical ablation of soft tissue by irreversible electroporation.

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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*"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."*

K240376

## 510(k) Summary

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

**There is no prior submission for the device.**

### 1 Submitter Information

- **510(k) Submitter/Holder:**  
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No.1 Xinxing Yilu Road, Emerging Industrial Cluster Area, Zonghan Subdistrict, Cixi City, Zhejiang, 315301,China
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Email: QARA@surgnova.com
- **Date Prepared:** Oct. 01, 2024

### 2 Proposed Device Information

**Trade/Proprietary Name:** Dopfi Electroporation System

**Common Name:** Low energy direct current thermal ablation device

**Model:** N3000

**Device Classification Names:** Low energy direct current thermal ablation device

**Regulations Number:** 21 CFR 878.4400

**Regulation Name:** Electrosurgical cutting and coagulation device and accessories

**Product Code:** OAB

**Device Class:** II

**Panel:** General & Plastic Surgery

### 3 Predicate Device

**510(k) Number:** K102329

**Device Trade/Proprietary Name:** NanoKnife® System

**Common Name:** Low energy direct current thermal ablation device

**Classification Name:** Electrosurgical Cutting and Coagulation Device and Accessories

**Regulation Number:** 21 CFR 878.4400

**Product Code:** OAB

**Regulatory Class:** Class II

**Panel:** General & Plastic Surgery

**Manufacturer:** AngioDynamics, Inc.

#### 4 Device Description

The Electroporation System consists of Electroporation Power Generator, Electroporation Trigger Probe, Electroporation Standard Probe, Electroporation Fixator support and Foot Switch. See following table for details:

Table 1 Electroporation System

	<b>Name</b>	<b>Model</b>
Electroporation System	Electroporation Power Generator	NPG3000
	Electroporation Trigger Probe	NTP13, NTP18, NTP25
	Electroporation Standard Probe	NSP13, NSP18, NSP25
	Electroporation Fixator support	NFS06
	Foot Switch	SJ-A01

The single-use Electroporation Trigger Probe with EO sterilization is the same as Electroporation Standard Probe and Electroporation Fixator support. The Electroporation Power Generator and Foot Switch are non-sterile and reusable.

With the Electroporation System, a voltage applied between pairs of probes in a series of pulses. The waveform of the voltage is adjustable as determined by clinician-chosen parameters. These parameters include volts, pulse width, pulse frequency and the distance between probes. Up to six probes may be placed in an array within the tissue. The probes of the array are matched as pairs by the system. When probes are activated via a foot switch, the scheduled voltage is delivered to tissue between subsequent pairs of probes. Soft tissue between the probes is ablated.

#### 5 Indications for use

The Dophi Electroporation System is intended for surgical ablation of soft tissue by irreversible electroporation.

## 6 Comparison list of the technological characteristics

Comparison Elements		Predicate Device NanoKnife System (K102329)	K240376 Subject Device
<b>Generator</b>			
Product Name		Generator	Electroporation Power Generator
Regulation No.		21 CFR 878.4400	21 CFR 878.4400
Classification		II	II
Product Code		OAB	OAB
Indications for Use		The NanoKnife System with six outputs is indicated for surgical ablation of soft tissue.	The Dophi Electroporation System is intended for surgical ablation of soft tissue by irreversible electroporation.
Technological characteristics	Working Principle	Equipment adopts the technology of the irreversible electroporation, to 1 mm in diameter of Probe into the soft tissue, and is estimated as the computer technology and mapping field size and location, the release of high voltage electrical impulses in the cell membrane lipid bilayer formed on nanoscale permanent perforation, destroy the balance in cells, induce apoptosis.	
	Working model	The system allow the User to select 90 PPM, 240 PPM, or ECG synchronization	Pulse mode: 90PPM ECG synchronization
	Probe number	Up to 6 monopole needles are supported simultaneously Port 1 contacts the trigger probe, and ports 2 to 6 connect to the standard electrode	Up to 6 monopole needles are supported simultaneously. Port 1 contacts the trigger probe, and ports 2 to 6 connect to the standard electrode.
	Pulse length	20-100us	20-100us
	Pulse number	10-100pcs	10-100pcs

	Electric field intensity	500-3000V/cm	700-3000V/cm
	Probe Pair Distance	0 cm ~ 3 cm	0 cm ~ 3 cm
	Exposed Length	0 cm ~ 4 cm	0 cm ~ 4 cm
	Voltage output	500-3000V	500-3000V
	Max Output Current	50A	50A
	Voltage supply:	100-240 V, 50/60 Hz	100-240V AC, 50/60Hz
<b>Probe</b>			
Product Name	Single Electrode Activation Probe; Standard Single Electrode Probe	Electroporation Trigger Probe; Electroporation Standard Probe	
Conditions of use	The standard Single Electrode Probe and Single Electrode Activation Probe are connected to the generator and intended for surgical ablation of soft tissue.	The Electroporation Probe is connected to the Electroporation power generator, and can be penetrated around the target lesion during the operation, and the high-voltage pulse energy outputted by the generator is transmitted to the target lesion	
Diameter	Single Electrode Activation Probe (Blue): 19G Standard Single Electrode Probe (White): 19G	Electroporation Trigger Probe (Orange): 19G Electroporation Standard Probe (White): 19G	
Specification	Single Electrode Activation Probe (Blue) 15 cm and 25 cm Standard Single Electrode Probe (White) 15 cm and 25 cm	Electroporation Trigger Probe (Orange): 13cm, 18cm, 25cm Electroporation Standard Probe (White): 13cm, 18cm, 25cm	
<b>Electroporation Fixator Support</b>			
Function	The spacer is used to ensure that the two probes are kept parallel and the pitch of the two probes can be	The Electroporation Fixator Support is used to ensure that the two probes are kept parallel and the pitch of the two probes	

	adjusted.	can be adjusted.
<b>Foot Switch</b>		
Function	The system incorporates a double trigger foot pedal system that prevents accidental delivery of procedure pulses. The foot pedals require the User to first arm the system by depressing the "Arm" foot pedal, and then sequentially, depressing the "Pulse" foot pedal within 10 seconds of arming to deliver energy to the patient.	The system uses a single pedal switch to control the excitation of test pulse and treatment pulse.  When the progress bar  appears on the screen, keep step on the Foot Switch until the progress bar reaches 100%  and the excitation pulse starts

## **7 Testing**

The Electroporation System has been designed and tested in accordance with both mandatory and voluntary standards, the following testing have been performed on the proposed device demonstrate substantial equivalence to the predicate devices, including:

### **Electrical Safety and Electromagnetic Compatibility:**

IEC 60601-1: 2020 Medical electrical equipment—Part 1: General requirements for basic safety and essential performance

IEC 60601-1-2: 2020 Medical electrical equipment—Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

IEC 60601-1-8: 2020 Medical electrical equipment – Part 1-8: General requirements for basic safety and essential performance – Collateral Standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems

### **Biocompatibility Testing:**

The compatibility of the skin-contact component material in the finished product meets the requirement of Biocompatibility. The biocompatibility tests are in compliance with the standards of ISO 10993-1: Biological Evaluation of Medical Devices and FDA guidance “Use of international Standard ISO 10993-1”, “Biological Evaluation of Medical Devices”.

### **Sterilization & Shelf Life:**

The Electroporation Probe and Electroporation Fixator support are sterilized by EO sterilization, and sterilization validation for the EO sterilization process has been conducted, and the result is in compliance with the ISO 11135 requirements. The sterilization process has been demonstrated  $SAL \leq 10^{-6}$ .

Primary package verification for Electroporation Probe and Electroporation Fixator support have been conducted, and the results conform to the ISO 11607 requirements. The transportation package verification also have been conducted to ensure the package integrity.

The shelf life of the Electroporation Probe and Electroporation Fixator support is 3 years. The accelerated aging and real-time aging test results demonstrate that the device is intact within the 3-year shelf life cycle to ensure the aseptic integrity of the initial packaging and the sterility of the device, the function of the device conforms to the requirements.

### **Software:**

The Software Validation is in compliance with FDA Guidance for the Content of Premarket

Submissions for Software Functions.

### **Animal testing**

The in-vivo animal study was conducted on porcine model. It includes chronic animal study and acute animal study, the chronic animal study includes the ablation volume measurement and ECG trigger mode testing between subject device group and predicate device group. The acute animal study was conducted to compare the potential thermal ablation effect of subject device and predicate device. The results show that the safety and efficacy of the tested articles are similar to those of the control articles.

### **Clinical Study**

Clinical studies were not required to demonstrate the substantial equivalence of the Electroporation System and the predicated device.

## **8 Determination of substantial equivalence**

Results of the performance testing demonstrated that the technological differences between the predicate and subject device do not raise new or different questions of safety or effectiveness. The subject device Electroporation System is as safe and effective and substantially equivalent to the predicate device NanoKnife System (K102329).