October 24, 2023

C2DX, Inc.
Mr. Brad Beale
General Manager
555 E Eliza St
Schoolcraft, Michigan 49087

Re: K233185
Trade/Device Name: SHAW SCALPEL SYSTEM CONTROLLER (MODEL SG6)

Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: September 28, 2023
Received: September 28, 2023

Dear Mr. Beale:

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: 2023.10.24 15:51:16 -04'00'

Mark Trumbore, Ph.D.
Assistant Director
DHT4A: Division of General Surgery Devices
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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)*
K233185

Device Name
SHAW SCALPEL SYSTEM CONTROLLER (MODEL SG6)

Indications for Use *(Describe)*
The Shaw Scalpel System Controller (Model SG6) is a surgical instrument designed to retain the precise, clean cutting characteristics of a traditional stainless steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut with minimal tissue damage and virtually no muscle stimulation, using heat thermally conducted to the tissue from an elevated temperature blade.

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

Reference: K233185

I. SUBMITTER

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1-901-261-0012

Submitted by: Mr. Brad Beale, General Manager
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Date Prepared: Oct 23, 2023

DEVICE
Reference: **K233185**
Name of Device: Shaw Scalpel System Controller (Model SG6)
Common or Usual Name: Shaw Scalpel System Controller
Regulatory Class: II
Product Code: GEI

II. PREDICATE DEVICE

The predicate device is the Hemostatix Model P8400 Thermal Scalpel System Controller.

a) Hemostatix Thermal Scalpel System Controller - Original 510 (k) K091107, cleared May 1, 2009.

The predicate device has not been subject to a design-related recall.

III. INTENDED USE

Both the Predicate Device (Hemostatix P8400 Thermal Scalpel System Controller) and the Subject Device (Shaw Scalpel System Controller Model SG6) have the same intended use:

The Hemostatix Thermal Scalpel System is a surgical instrument designed to retain the precise, clean cutting characteristics of a traditional stainless steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut with minimal tissue

damage and virtually no muscle stimulation, using heat thermally conducted to the tissue from an elevated temperature blade.

IV. DEVICE DESCTRIPTION

The Shaw Scalpel System Controller (Model SG6) is a surgical instrument designed to retain the precise, clean cutting characteristics of a traditional steel scalpel and to minimize blood loss by simultaneously sealing blood vessels as they are cut with minimal tissue damage and virtually no muscle stimulation, using heat thermally conducted to the tissue from an elevated-temperature blade. The system utilizes a razor-sharp blade coated with proprietary thick-film inks which when used with the handle and controller heat the blade to precisely controlled temperature levels to achieve the desired levels of hemostasis during surgery. The temperature of the Shaw Scalpel System's blade can be adjusted from 70° C to 300° C at the touch of button on the handle or the controller.

The Shaw Scalpel System is intended to provide hemostasis as the surgeon incises. The sharpness of the steel blade and scalpel pressure provides the incising action. The steel blade is covered with a black non-stick coating. Below the non-stick coating surface and a layer of insulation is temperature-controlled micro- circuitry which transfers heat uniformly to the entire blade.

1. <u>The Shaw Scalpel System consists of the following main components:</u>

   a) **Controller** – An electronic power supply/controller that energizes the blade and provides various automatic calibration, sensing, and control functions. It has user controls with visual and audible indications of instrument status. The controller includes software installed on a PCBA. The software monitors the resistance of the blade which it uses to calculate the amount of power needed to be applied to the blade to maintain the temperature setting on the controller.

   b) **Disposable Handle and Blade** – Both the subject and the Predicate Controllers utilize a sterile disposable scalpel handle and blade, connected to the controller with a light- weight, flexible electrical cable for use with disposable blades. Handles and blades were cleared via 510 (k) K002021.

   c) **Footswitch** – An optional footswitch is available for use with the Controller which allows the user to increase/decrease the blade temperature and to switch from CUT and COAG modes. The footswitch was cleared via K091107.

2. <u>Comparison of the Technological Characteristics with the Predicate Device</u>

   a) Overall size and shape of the outer enclosure of the subject controller is different, but not significantly;
   b) Subject Controller utilizes a capacitive USB touch screen interface;
   c) Handle and blade compatibility are the same for both the subject and predicate controller;
   d) Both the subject and the predicate devices utilize the same audible tonal signals to designate the above mentioned conditions;

e) Both the subject and the predicate devices meet IEC 60601-1 and IEC 60601-1- 2 electrical safety standards;
f) No new risks identified with the subject device as compared with the predicate device;
g) Both the subject and predicate devices provided heat to the blade from in 10° C increments from 70°C to 300° C; and,
h) Both the subject and predicate devices have the same intended use.

3. Software

For both the subject and predicate devices, software is housed on a PCBA within each controller. This Software is responsible for monitoring the temperature sensors and controlling the amount of power applied to the heater circuits on the scalpel blades during surgery and for providing a simple user interface.

Software in both the subject and predicate devices are considered to be a Moderate Level of Concern. Software in the subject device was validated and complies with AAMI/IEC 62304:2006 & A1:2016, Medical device software - Software life-cycle processes.

4. Packaging

Both the predicate and subject devices are packaged in a Styrofoam insert within a cardboard shipping box. Shipping tests for both were performed in accordance with the FedEx International Safe Transit Association (ISTA) Procedure 6A, Packaged- Products 150 lbs or less, 2006.

5. Sterilization

Neither the subject nor predicate devices are provided sterile as they are not used in the sterile surgical field.

V. SUBSTANTIAL EQUIVALENCE

The modified Controller has the following similarities to those which previously received 510(k) clearance:

Comparison to Predicate device P8400, **K091107**:	Subject Device Shaw Scalpel System, Model SG6, **K233185:**
Intended Use	Identical
Scientific Technology	Identical
Operating Principle	Identical
Power Modality	Identical
Operating Temperature Ranges	Identical (70°C to 300° C)
Compatible Blades and Handles	Identical (see K002021)
Design Control Activities to include verification testing	Identical, (Electrical Safety and EMC Testing to latest revision of Standards)
Risk Management	No new risks identified

In summary, the *C2Dx Shaw Scalpel System Controller (Model SG6)* described in this submission is, in our opinion, substantially equivalent to the predicate devices.

VI. SUMMARY OF DESIGN CONTROL ACTIVITIES:

1. Risk Analysis

   Risk Assessment performed in accordance with ISO 14971:2019, Medical Devices - Application of Risk Management to Medical Devices revealed no new risks with the subject device versus the predicate device.

2. Summary of Verification Testing

   Results of verification testing indicate that the modified devices meet the established performance requirements.

   a) Electrical Safety

   The Shaw Scalpel System and newly modified controller was tested by an independent laboratory and found in compliance with the following:

   - **IEC 60601-1 2005, AMD1: 2012, AMD2: 2020** – Medical electrical equipment - Part 1: General requirements for basic safety and essential performance CONSOLIDATED EDITION.
   - **IEC 60601-1-2 (2014) + A1:2020** – Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and tests

   b) Summary of Non-clinical Tests

   i) Actual Blade Temp vs Controller Set-point

   Actual blade temperature as compared to controller set-point was measured with current blades. Temperatures were evaluated at controller set-point temperatures of 100°, 200°, and 300° C and were found to be within the previously established acceptance criteria of +10°, -20° C temperature range. Therefore, the acceptance criteria for this test were met.

   The test methods used are the same as those submitted in the original predicate device submission.

   ii) Human Factors Usability Testing

   C2Dx performed Usability and Human Factors Testing for the development of the subject controller. This research followed ANSI

AAMI HE75 practices to maximize the likelihood that it will be safe and effective for the intended users, uses and use environments.

Two user groups, non-sterile (circulating nurses) and sterile (scrub techs and surgeons) with 15 people in each group were involved in the study. The sterile group consisted of 15 circulating nurses, and the non-sterile group consisted on 11 scrub techs and 4 surgeons. In all, a total of 30 people participated in the study.

Conclusions:

All acceptance criteria were met for Usability Testing for safe and effective use of the device.

VII. CONCLUSIONS

Based upon the information submitted herein and the results of performance testing, we conclude that the subject device is substantially equivalent to the predicate devices under the Federal Food, Drug, and Cosmetic Act.

End