October 23, 2023

Kono Seisakusho Co., Ltd
Aya Takagi
Development & Pharmaceutical Affairs Group Member
2-11-10
Soya
Ichikawa city, Chiba 272-0837
Japan

Re: K230281
Trade/Device Name: Picoclamp
Regulation Number: 21 CFR 870.4450
Regulation Name: Vascular clamp
Regulatory Class: Class II
Product Code: DXC
Dated: September 22, 2023
Received: September 22, 2023

Dear Aya Takagi:

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,

Rachel E. Neubrander -S

Rachel Neubrander
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular 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)*
K230281

Device Name
PICOCLAMP

Indications for Use *(Describe)*
A surgical instrument used to occlude a blood vessel temporarily.

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:

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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."

K230281

510(k) SUMMARY

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

I. SUBMITTER

Kono Seisakusho Co., Ltd.
2-11-10 Soya, Ichikawa City, Chiba 272-0832, Japan
Tel: *+81-47-372-3281*
Fax: *+81-47-373-4515*

Contact Person: Aya Takagi
Development and Pharmaceutical Affairs Group Member
Date Prepared: October 19th, 2023

II. DEVICE

Device Trade Name:	PICOCLAMP
Device Common Name:	Clamp, Vascular
Classification Name:	Vascular clamp
Regulation:	21 CFR §870.4450
Regulatory Class:	Class II
Device Panel:	Cardiovascular
Product Classification Code:	*DXC*

III. PREDICATE DEVICE

Predicate Manufacturer:	AROS Surgical Instruments Corporation
Predicate Trade Name:	Vein Clamp and Artery Clamp
Predicate 510(k):	K161315

IV. DEVICE DESCRIPTION

PICOCLAMP is Ethylene Oxide sterile single-use hemostasis clamp consisting of Polyetheretherketone (PEEK) and stainless steel (SUS series). PICOCLAMP is designed for use during surgery to temporarily occlude blood vessels during the anastomosis process. PICOCLAMP consists of three main direct patient-contacting parts, all of them are streilized; main body, axis, and spring. The body is consisting of two parts; the jaw which is used to occlude the blood vessel temporarily and the grip which functions to open and close jaws using the surgeon hand or the clamp forceps. The axis integrates the body and keep its parts intact. The spring functions to give clamping force to the jaws. Two types of clamps are provided: green color clamps used for arteries temporary occlusion and blue color clamps used for veins temporary occlusion. Both of the artery and vein clamp are having two types: single and double. PICOCLAMP is available in three different sizes; S (Small), M (Medium), and L (Large). PICOCLAMP is used for temporary occlusion of blood vessels with diameters ranging from 0.2mm to 2.0mm. The clipping power applied at the blood vessel differs depending on the size of the clamp and the pressure of the spring selected. Once the anastomosis process is complete, PICOCLAMP is removed from the patient.

V. INDICATIONS FOR USE

A surgical instrument used to occlude a blood vessel temporarily.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVCE

In terms of technological characteristics, PICOCLAMP does not completely share them with the predicate device. The main differences are the material used for the clamp body, using different sterilization method and a slight change in the device design.

The proposed device's body is made of PEEK (Polyether ether ketone), while the predicate device is made of poly carbonate. Based on the Biocompatibility testing results, Kono Seisakusho Co., Ltd. considers that using different material does not raise different questions of the safety and effectiveness of the proposed device.

The sterilization method of the proposed device is Ethylene Oxide (EO), while the predicate device sterilization method is by radiation. Ethylene Oxide residuals testing results shows that the difference of the sterilization method does not affect the safety and effectiveness of the proposed device.

The proposed device's body contains "hook" at the top of its jaw to help holding the blood vessel. Bench performance testing results of both the proposed device and the predicate device shows that this design change does not impact the proposed device's performance.

<table>
<tr><th></th><th>Proposed Device</th><th>Predicate Device</th></tr>
<tr><td>Trade Name</td><td>PICOCLAMP</td><td>Vein Clamp and Artery Clamp</td></tr>
<tr><td>Intended Use/Indication for Use</td><td>A surgical instrument used to occlude a blood vessel temporarily</td><td>A surgical instrument used to occlude a blood vessel temporarily</td></tr>
<tr><td>Raw Material</td><td>Main Body: Polyetheretherketone (PEEK)
Axis: 300 Series Stainless Steel
Spring: 300 Series Stainless Steel</td><td>Main Body: Stainless steel and polycarbonate resin
Shaft: Acrylonitrile butadiene styrene, stainless steel or titanium
Spring: stainless steel and titanium</td></tr>
<tr><td>Application</td><td>Artery clamps: Green
Vein Clamps: Blue</td><td>Artery Clamps: Yellow
Vein Clamps: Green</td></tr>
<tr><td>Blood Vessel Diameter</td><td><table><tr><th>Size</th><th>Blood Vessel Diameter (mm)</th></tr><tr><td>L</td><td>1.0~2.0</td></tr><tr><td>M</td><td>~1.0</td></tr><tr><td>S</td><td>0.2~1.0</td></tr></table></td><td><table><tr><th>Product Code</th><th>Blood Vessel Diameter (mm)</th></tr><tr><td>TIM、TKM</td><td>1.0～2.0</td></tr><tr><td>TIS、TKS</td><td>0.5～1.0</td></tr><tr><td>TKF</td><td>0.2～0.9</td></tr></table></td></tr>
<tr><td>Sterilization</td><td>Ethylene Oxide (EO)</td><td>Radiation</td></tr>
</table>

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Sterilization & Shelf-life & Packaging Testing
Testing reports demonstrate compliance to the standards listed below.

- ISO 11135 Second edition 2014-07-15 Sterilization of health care products- Ethylene oxide -Requirements for development, validation and routine control of a sterilization process for medical devices
- ISO 10993-7 Second edition 2008-10 Biological evaluation of medical devices -- Part 7: Ethylene oxide sterilization residuals
- ISO 11607-1 Second edition 2019-02 Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems
- ISO 11607-2 Second edition 2019-02 Packaging for terminally sterilized medical devices -- Part 2: Validation requirements for forming, sealing and assembly processes
- ASTM F1980-21 Standard Guide for Accelerated Aging of Sterile Barrier Systems and Medical Device
- ASTM F2096-11 (Reapproved 2019) Standard Test Method for Detecting Gross Leaks in Packaging by Internal Pressurization (Bubble Test)
- ASTM F1886/F1886M-16 “Standard Test Method for Determining Integrity of Seals for Flexible Packaging by Visual Inspection
- ASTM F88-15 Standard Test Method for Seal Strength of Flexible Barrier Materials
- ASTM F1929-15 Standard Test Method for Detecting Seal Leaks in Porous Medical Package by Dye Penetration
- ASTM D4332-22 Standard Practice for Conditioning Containers, Packages, or Packaging Components for Testing
- ASTM D4169-22 Standard Practice for Performance Testing of Shipping Containers and Systems

Biocompatibility Testing
The following biocompatibility testing was conducted to demonstrate substantial equivalence with the predicate device:
Cytotoxicity, Sensitization, Intracutaneous irritation, Acute systemic Toxicity, Pyrogenicity

Bench Performance Testing

Since no guidance documents or FDA recognized consensus standards exist for the device type, structural and dimensional confirmation, clipping power testing, ability for repeated clamp opening and closing, and resistance to dislodgement testing were conducted as performance testing. Testing reports of both the proposed device (PICOCLAMP) and the predicate device demonstrate that PICOCLAMP is substantially equivalent to the predicate device.

Animal Performance Testing
Animal performance testing was not required to demonstrate safety and effectiveness of the device.

Clinical Performance Testing
Clinical testing was not required to demonstrate the safety and effectiveness of the device.

VIII. CONCLUSIONS

After performing non-clinical performance testing, Biocompatibility testing, Sterilization and Shelf-life testing, the data shows that PICOCLAMP is substantially equivalent to the predicate device.