November 7, 2024

Newclip Technics
Robert Poggie
Regulatory Consultant to Newclip Technics
PA de la Lande Saint Martin
45 rue des Garottieres
Haute Goulaine, 44115
France

Re: K240415
Trade/Device Name: Newclip Patient-matched instrumentation non sterile PSI
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PBF
Dated: October 8, 2024
Received: October 8, 2024

Dear Robert Poggie:

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) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Shumaya Ali -S

Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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.

Submission Number *(if known)*

K240415

Device Name

Newclip Patient-matched instrumentation non sterile PSI

Indications for Use *(Describe)*

The Newclip Patient-matched instrumentation non sterile PSI is indicated to be used as a surgical instrument to assist in pre-operative planning and/or in guiding surgical instruments in High Tibial Medial Opening or Closing Wedge Osteotomy, Distal Femoral Medial or Lateral Closing Wedge Osteotomy, Distal Femoral Lateral Opening Wedge Osteotomy and Distal Femoral Medial or Lateral Derotational Osteotomy, when the anatomic landmarks necessary for pre-operative planning can be clearly identified on the patient's radiographic images (i.e., computed tomography (CT)). Each PSI is designed to be compatible with implants from the Newclip High Tibial Osteotomy System or the Newclip Activmotion Range.

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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K240415 - 510(k) Summary
Newclip Patient-matched instrumentation non sterile PSI

In accordance with 21 CFR 807.92, the following information is a 510(k) Summary for the Newclip Patient-matched instrumentation non sterile PSI.

A. SUBMITTER INFORMATION

Sponsor Name:	NEWCLIP TECHNICS
Sponsor Address:	P.A. de la Lande Saint Martin, 45 rue des Garottières, F-44115 Haute-Goulaine, FRANCE
Submitter Name:	BioVera, Inc.
Submitter Address:	65 Promenade Saint-Louis, Notre-Dame-De-L'Ile-Perrot, QC, J7W 3J6, CANADA
Contact Person:	Robert A. Poggie, PhD
Phone & Fax Number:	(514) 901-0796
Date of Preparation:	October 8th, 2024

B. DEVICE IDENTIFICATION

Device Trade Name:	Newclip Patient-matched instrumentation non sterile PSI
Device Common Name:	Orthopaedic Surgical Planning and Instrument Guides
Classification Code:	PBF
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
Classification Panel:	Orthopedic
Regulation:	21 CFR 888.3030

C. PREDICATE DEVICE

K221615 (Primary)	Newclip Patient-matched instrumentation non sterile PSI
K163156	SurgiCase Orthopaedics, SurgiCase Connect, SurgiCase Guides (Materialise N.V).

D. DEVICE DESCRIPTION

The Newclip Patient-matched instrumentation non sterile PSI are patient-matched devices (PSI Guides). The PSI Guides are surgical drilling/cutting guides that are additively manufactured (3D printed) and are designed to match the patient's anatomy. They are intended to assist in pre-operative planning and/or in guiding the marking of bone and/or guiding surgical instruments in non-acute, non-joint replacing osteotomies around the knee. They are single-use devices provided non sterile for sterilization by health care professionals before use. The Newclip Patient-matched instrumentation non sterile PSI can be used to facilitate implantation of the Newclip Activmotion Range devices.The primary purpose of this 510(k) notification is to add PSI Guides for closing-wedge and derotation osteotomies.

Material: Polyamide (PA2200).

E. INDICATIONS FOR USE

The Newclip Patient-matched instrumentation non sterile PSI is indicated to be used as a surgical instrument to assist in pre-operative planning and/or in guiding surgical instruments in High Tibial Medial Opening or Closing Wedge Osteotomy, Distal Femoral Medial or Lateral Closing Wedge Osteotomy, Distal Femoral Lateral Opening Wedge Osteotomy and Distal Femoral Medial or Lateral Derotational Osteotomy, when the anatomic landmarks necessary for pre-operative planning can be clearly identified on the patient's radiographic images (i.e., computed tomography (CT)). Each PSI is designed to be compatible with implants from the Newclip High Tibial Osteotomy System or the Newclip Activmotion Range.

F. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The Newclip Patient-matched instrumentation non sterile PSI have the same or similar technological characteristics as the predicate devices.

Target population: The Newclip Patient-matched instrumentation non sterile PSI are intended for the same subset of the target population (i.e. adults only) of the predicate devices.

Material: The Newclip Patient-matched instrumentation non sterile PSI uses the same additively manufactured (AM) Polyamide material as the predicate devices.

Manufacturing method: The Newclip Patient-matched instrumentation non sterile PSI are manufactured using the same AM method as the predicate devices.

Imaging technique: The Newclip Patient-matched instrumentation non sterile PSI uses the same image technique (CT) as the predicate device (K221615).

Comparison of the technological characteristics and indicated use of the subject and predicate devices demonstrate that the subject device is substantially equivalent to the predicate device.

G. PERFORMANCE DATA

Verification and validation (V&V) activities included the following:

- Surgeon evaluation of precision and accuracy based on simulated-use cadaver surgeries of worst-case surgical approach and type of PSI-guide. Precision and accuracy of the subject device was demonstrated. The guides used in these studies were identical to the subject device in terms of design, material, methods of construction, patient matching process, manufacturing, and surgical technique.
- An analysis was performed to compare the subject devices and the predicate devices regarding verification of precision and accuracy in design and manufacturing as well as regarding cleaning and sterilization. The analysis showed that the subject devices are as safe and as effective as the predicate device described in K221615.

H. CONCLUSION

The information presented in this 510(k) notification show the Newclip Patient-matched instrumentation non sterile PSI to be substantially equivalent to the legally marketed predicate devices.