



October 25, 2023

Newclip Technics
% Robert A. Poggie, PhD
President
BioVera, Inc.
65 Promenade Saint-Louis
Notre-Dame-De-L'Ile-Perrot, QC, J7W 3J6
Canada

Re: K221615

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: September 22, 2023
Received: September 22, 2023

Dear Dr. 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.

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

Indications for Use

510(k) Number (if known)

K221615

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 Wedge Osteotomy and Distal Femoral Lateral Opening Wedge 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.

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510(k) Summary for K221615
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 23rd, 2023

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

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. The subject devices 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 guiding surgical instruments in orthopaedic surgery (High Tibial Medial Opening Wedge Osteotomy and Distal Femoral Lateral Opening Wedge Osteotomy). 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 Newclip High Tibial Osteotomy System or the Newclip Activmotion Range devices.

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 Wedge Osteotomy and Distal Femoral Lateral Opening Wedge 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 of the predicate device.

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 device.

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

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

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

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 human clinical cases.
Precision and accuracy of the subject device was demonstrated in published human clinical studies by surgeon-users on patients in Europe using Newclip Patient-matched instrumentation non sterile PSI guides. 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.
- Verification of precision and accuracy in design and manufacturing.
Intra and inter designer variability of the segmentation and design processes were evaluated on worst-case CT scans and worst-case models of the subject PSI guides.
- Verification testing demonstrating acceptable wear in simulated use surgeries.
The amount of polymer debris was measured after simulated surgery using worst case designed and additively manufactured subject PSI guides.
- Cleanliness and sterilization of the additively manufactured subject devices.
- Dimensional verification of worst case devices in manufacture and after sterilization.

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 device.