



March 14, 2025

Monogram Orthopaedics, Inc
Nisha Patel
Director Of Quality Assurance & Regulatory Affairs
3913 Todd Lane
Ste 307
Austin, Texas 78744

Re: K242121
Trade/Device Name: mBôs (Monogram mBôs TKA System)
Regulation Number: 21 CFR 882.4560
Regulation Name: Stereotaxic Instrument
Regulatory Class: Class II
Product Code: OLO
Dated: February 24, 2025
Received: February 25, 2025

Dear Nisha Patel:

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

Indications for Use

Submission Number (if known)

K242121

Device Name

mBôs (Monogram mBôs TKA System)

Indications for Use (Describe)

The mBôs TKA system is indicated for use in surgical knee procedures on adults in which the stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy.

These procedures include:

Total Knee Arthroplasty (TKA)

The implant systems compatible with the system:

mPress™ Total Knee System:

mPress™ TL: Cementless

mPress™ TC: Cemented

Each Implant System includes the Cruciate Retaining (CR), Cruciate Substituting (CS), and Posterior Stabilized (PS) implant types.

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 - K242121

Device Trade Name:	mBôs (Monogram mBôs TKA System)
Manufacturer:	Monogram Orthopaedics Inc. 3913 Todd Lane, Suite 307, Austin, TX 78744
Contact:	Nisha Patel Director QA/RA Email: nisha@monogramorthopedics.com Phone: +1 (512) 790-5151
Prepared by:	Nisha Patel
Date Prepared:	February 24, 2025
Classifications:	Orthopedics
Class:	II
Product Codes:	OLO
Primary Predicate:	K143752
Product Name:	mBôs TKA System

INDICATIONS FOR USE

The mBôs TKA system is indicated for use in surgical knee procedures on adults in which the stereotactic surgery may be appropriate, and where reference to rigid anatomical bony structures can be identified relative to a CT based model of the anatomy.

These procedures include:

- Total Knee Arthroplasty (TKA)

The implant systems compatible with the system:

- mPress™ Total Knee System:
 - mPress™ TL: Cementless
 - mPress™ TC: Cemented

Each Implant System includes the Cruciate Retaining (CR), Cruciate Substituting (CS), and Posterior Stabilized (PS) implant types.

510(k) Summary

INTENDED USE

The mBô's TKA system is a stereotactic planning and implementation device intended to assist surgeons with primary total knee arthroplasty (TKA). It is an alternative to manual TKA template planning and bone preparation for TKA surgeries. This system aids surgeons with virtual implant placement, determining the relative position and orientation of anatomical structures, and bone preparation.

DEVICE DESCRIPTION

The mBô's TKA system is a stereotactic planning and implementation device designed to assist orthopedic surgeons in treating patients requiring primary total knee arthroplasty (TKA) surgeries. It is an alternative to manual template planning for femur and tibia bone preparation for TKA surgical procedures.

The device's hardware comprises a robotic arm mounted on a stabilized cart with an integrated sagittal saw-based cutting system. The robot cart houses the necessary electromechanical components. It provides power and communications to an infrared (IR) based optical tracker, a display screen, a foot pedal, a touchscreen, a sagittal saw cutting tool, and protective stops. Additionally, the system includes dedicated instrumentation, tools, accessories, and proprietary software for operating and case planning.

The mBô's TKA system proprietary software suite (mSuite™) is comprised of the following:
mPower® Case Management Application (CMA)
mPower® Embedded System Applications

Predicate Device: Mako TKA System™: K143752

PERFORMANCE TESTING SUMMARY:

Design verification was confirmed by examining and providing objective evidence that specified requirements were fulfilled. Tests performed for assessing device performance are included in the Design Verification and Validation Report (DS-00230, Rev 02), which includes Performance Testing, Functional Testing, Electrical Safety Testing, Electromagnetic Compatibility (EMC) Testing, Reliability Testing, Accuracy Testing, Software and Cybersecurity Testing, Biocompatibility, Sterilization, Cleanability, Packaging, and more. All users (surgeons, sterile staff, and Monogram representation) successfully used the mBô's TKA System to perform Simulated Use, Human Factors Summative Validation, and Design Validation studies focusing on the system safety and efficacy on synthetic and human cadaveric knees.

SUBSTANTIAL EQUIVALENCE:

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The Monogram mBôs TKA System (subject device) and the MAKO TKA System™ (predicate device) are both intended for use in Total Knee Arthroplasty (TKA) surgeries.

Both devices utilize stereotactic (computer-assisted) devices to precisely track bone structures relative to the stereotactic devices throughout the surgery.

The systems feature substantially equivalent configurations, including one or two stations equipped with an IR tracking camera, foot pedal, robotic arm, computer units, power supply, and display monitors. They both use dedicated instrument sets containing arrays with reflective infrared (IR) markers and tools such as bone pins and clamps to attach these arrays to the patient's bony anatomy. The Monogram mBôs System and the MAKO TKA System™ also incorporate a dedicated cabled robot-mounted End Effector.

The operation of both systems is substantially equivalent. Using patient specific information from a pre-operative CT scan allows the surgeons to evaluate bone structure, disease severity, joint alignment and virtual implant fit. Surgeons use a navigated probe to register bone anatomy, and both systems feature software to generate virtual bone models to assist in planning the TKA resections. Following surgical planning, both systems suspend the cutting tool instrument in space and hold the trajectory, allowing the user to advance towards or away from the patient while holding alignment to the patient to perform the planned resection. Both devices utilize a foot pedal to navigate surgical workflows, including collecting registration points, capturing checkpoints, and navigating surgical workflows.

The cutting tool's impact on the bone is comparable for both systems. Both the subject device and predicate utilize robot-mounted sagittal saw blade end effectors. The predicate device uses a mechanical trigger for sagittal saw actuation and the subject device uses a manual force-based trigger in conjunction with the foot pedal for sagittal saw actuation. Both systems allow the surgeon to directly retract the end-effector from the cut site. Both systems constrain the end-effector within virtual boundaries established for each resection. The navigation feedback of both systems is substantially equivalent. Both systems detect bone motion during cutting. Both systems display alerts for implant position or selection errors (femur notching, size incompatibility). The navigation software in both the proposed and predicate devices facilitates virtual implant placement to establish the desired resection planes, track the real-time position of registered arrays, and adjust the orientation of the suspended End-Effector (Handpiece) and blade relative to the planned resection plane to accommodate any movement of the patient's leg.

The surgical workflows of both systems are substantially equivalent. The predicate and subject devices both feature a Graphic User Interface (GUI) that enables surgeons to select the types and sizes of implants and the order of cuts depending on clinical

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preference. The surgical techniques offered by the proposed and predicate devices are tailored to the specific implants indicated for use with each respective system.

The devices have slight differences in how they establish a resection plane. In the predicate device, a robot arm suspends a Saw Handpiece (MICS Handpiece), allowing the user to advance towards or away from the patient while holding alignment to the patient to perform the planned resection within virtual control boundaries (haptic boundaries); the saw is not free to violate the haptic boundaries associated with the resection plane. Similarly, in the subject device, a robot arm suspends an End Effector, allowing the user to advance towards or away from the patient while holding alignment to the patient to perform the planned resection; however, the saw is not free to violate linear paths within bone boundaries associated with the resection plane. The user advances the tool towards or away from the patient via foot pedal control or away from the patient by hand-guided control. Several tests were conducted to support the substantial equivalence of the subject device to the predicate, including Cadaveric Cut Accuracy, System End-to-End Accuracy, Robot Arm Positional Accuracy, Cutting Tool Positional Accuracy, Registration Accuracy, Hardware Reliability Testing, Positional Repeatability Testing, Blade Cut-Path Verification, and Soft Tissue Assessment Validation. These differences do not impact on the safety or effectiveness of the devices.

The Monogram mBôs Total Knee Arthroplasty (TKA) System performed a comprehensive risk assessment, conforming to ISO 14971:2019 and the Monogram Orthopaedic Risk Management procedure, analyzing and mitigating potential risks associated with its use. All clinical hazards were documented and addressed, determining that the system overall residual risk is acceptable. A detailed comparison with the MAKO TKA System™ robotic-assisted solution established substantial equivalence based on intended use, technological characteristics, the principle of operation, and Safety & Performance testing.

CONCLUSION:

Based on the analysis performed, the subject Monogram mBôs TKA system is substantially equivalent to the predicate Mako TKA System™ K143752.