Biomet Manufacturing Corp.
℅ Ms. Katherine Choi
Senior Regulatory Affairs Specialist
56 East Bell Drive
WARSAW IN 46581

June 25, 2023

Re: K230540
Trade/Device Name: Patient Specific Planning Solution™ Bone Models
Regulation Number: 21 CFR 892.2050
Regulation Name: Medical image management and processing system
Regulatory Class: Class II
Product Code: LLZ
Dated: June 13, 2023
Received: June 14, 2023

Dear Ms. Choi:

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 (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 located 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.

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 803) for

devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 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,

Jessica Lamb, Ph.D.
Assistant Director
Imaging Software Team
DHT8B: Division of Radiological Imaging
Devices and Electronic Products
OHT8: Office of Radiological Health
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.

Submission Number *(if known)*

K230540

Device Name

Patient Specific Planning Solution™ Bone Models

Indications for Use *(Describe)*

The PSPS bone model is indicated, based on patient-specific radiological images (CT scans), to assist in pre-operative orthopedic planning for patients able to undergo orthopedic procedures and able to be radiologically scanned.

The PSPS bone model is a diagnostic tool to visually aid in orthopedic pre-operative surgical planning for skeletally mature individuals.

Be advised, the quality of medical images determines the accuracy of the 3D bone models. Zimmer Biomet recommends using CT Protocol PMI® Patient-Matched Implants CT Protocol. Only images obtained less than six (6) months prior should be used for simulating and/or evaluating orthopedic treatment options.

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) #: K230540

510(k) Summary

Prepared on: 2023-06-14

Contact Details

21 CFR 807.92(a)(1)

Applicant Name	Biomet Manufacturing Corp.
Applicant Address	56 East Bell Drive Warsaw IN 46581 United States
Applicant Contact Telephone	260-602-2359
Applicant Contact	Ms. Katherine Choi
Applicant Contact Email	Katherine.Choi@ZimmerBiomet.com
Correspondent Name	Biomet Manufacturing Corp.
Correspondent Address	56 East Bell Drive Warsaw IN 46581 United States
Correspondent Contact Telephone	609-579-8095
Correspondent Contact	Mr. Caleb Barylski
Correspondent Contact Email	Caleb.Barylski1@zimmerbiomet.com

Device Name

21 CFR 807.92(a)(2)

Device Trade Name	Patient Specific Planning Solution™ Bone Models
Common Name	Medical image management and processing system
Classification Name	System, Image Processing, Radiological
Regulation Number	892.2050
Product Code	LLZ

Legally Marketed Predicate Devices

21 CFR 807.92(a)(3)

Predicate #	Predicate Trade Name (Primary Predicate is listed first)	Product Code
K183105	Mimics Medical	LLZ

Device Description Summary

21 CFR 807.92(a)(4)

The Patient Specific Planning Solution™ 3D Bone Model is a 3-dimensional representation of the requested anatomical bone site. The Bone Models are diagnostic tools to allow the Surgeon to physically and visually aid in pre-operative orthopedic planning to facilitate the implantation of medical devices.

The Patient Specific Planning Solutions™ are designed and manufactured of polyamide (nylon) using additive manufacturing (selective laser sintering), based on the approved/finalized orthopedic pre-surgical plan and shipped prior to surgery. The Bone Models are provided non-sterile and are used pre-operatively for education, visualization, planning to aid in component selection, sizing, and placement based on patient specific radiological images (CT scan). Physical bone models' critical bony areas are printed at <1mm mean deviation.

The full-scale 3D printed Patient Specific Bone Model is shipped to the surgeon prior to the patient's surgery to facilitate pre-operative

planning.

Intended Use/Indications for Use

21 CFR 807.92(a)(5)

The PSPS bone model is indicated, based on patient-specific radiological images (CT scans), to assist in pre-operative orthopedic planning for patients able to undergo orthopedic procedures and able to be radiologically scanned.

The PSPS bone model is a diagnostic tool to visually aid in orthopedic pre-operative surgical planning for skeletally mature individuals.

Be advised, the quality of medical images determines the accuracy of the 3D bone models. Zimmer Biomet recommends using CT Protocol PMI® Patient-Matched Implants CT Protocol. Only images obtained less than six (6) months prior should be used for simulating and/or evaluating orthopedic treatment options.

Indications for Use Comparison

21 CFR 807.92(a)(5)

Intended Use: Similar
Conclusion: The intended use of the subject device partially consists of the intended of use of the predicate device. The subject device uses the predicate device software in the creation of the physical bone model used for diagnostic purposes.

Indications for Use:Similar
Conclusion: The subject device utilizes the Mimics Medical software interface and image segmentation system in the creation of images to develop a physical bone model replica for use as a diagnostic tool by the surgeon. The predicate device allows the production of 3D models in orthopedic, maxillofacial, and cardiovascular applications.

Technological Comparison

21 CFR 807.92(a)(6)

The technological characteristics for both the subject and predicate device are identical in terms of device functionality, imaging modality, imaging information transfer, and design features. The subject device utilizes the predicate device to import CT scans, visualize and segment medical images, check and correct the segmentations, and create digital 3D models for measuring, treatment planning, and producing the output file for 3D bone model creation.

Non-Clinical and/or Clinical Tests Summary & Conclusions

21 CFR 807.92(b)

Summary of Performance Data:
The subject and predicate device utilize the same geometric accuracy of models testing. Additional design verification testing and test method validation were performed on the subject device to further ensure geometric and design accuracy, including material, burrs and sharp edges, CT scanning requirements, bone model geometric specification, design, and formative evaluation testing. Test method validation testing included assessment of the workflow from input digital 3D file to output physical replica. These verification and validation activities demonstrate that the subject device performs as intended for the desired indications.

Clinical Tests:
N/A

Conclusion of Safety and Effectiveness:
The subject device, Patient Specific Planning Solution™ Bone Models, has identical technological characteristics to the predicate device, Mimics Medical (K183105). The subject device has similar Intended Use, Indications for Use, and performance requirements as its predicate device and the information provided demonstrates:
• any differences do not raise new questions of safety and effectiveness; and
• the proposed device is at least as safe and effective as the legally marketed predicate device.