June 12, 2025

Biocomposites Ltd.
Melisa Lamanna
Research and Development Manager
Keele Science Park
Keele, Staffordshire ST5 5NL
United Kingdom

Re: K242865
Trade/Device Name: Synicem Hip Spacer; Synicem Knee Spacer; Synicem Shoulder Spacer
Regulation Number: 21 CFR 888.3360
Regulation Name: Hip Joint Femoral (Hemi-Hip) Metallic Cemented Or Uncemented Prosthesis
Regulatory Class: Class II
Product Code: KWL, KWY, JWH, HSD, KWS
Dated: May 14, 2025
Received: May 15, 2025

Dear Mrs. Lamanna:

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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2025.06.12 09:44:17 -04'00'

For: Jesse Muir, Ph.D.
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)*

K242865

Device Name

Synicem Hip Spacer, Knee Spacer, Shoulder Spacer

Indications for Use *(Describe)*

The Hip Spacer with gentamicin preserves the joint space and the length of the affected limb, which results in the maintenance of the entire abductor and stabilizer apparatus of the hip. Its use is indicated for a limited period, in patients who require a two-stage Revision Arthroplasty. A systemic antibiotic therapy should also be prescribed while the spacer remains implanted. The Hip Spacer is implanted after the removal of the infected implant, as a regular Hemiarthroplasty. The spacer is inserted into the femoral canal, and a handmade ring of PMMA bone cement with antibiotic may be added to the base of the spacer's neck in order to increase stability. The spacer is kept "in place" until it is replaced by the final prosthesis according to medical criteria. The Hip Spacer must not remain implanted for more than 6 months. Once this period has elapsed, it must be explanted and a permanent device implanted or another appropriate treatment performed.

The Knee Spacer with gentamicin maintains the articular space, the length of the affected limb, and the ligament apparatus of the knee. Its use is indicated for a limited period, in patients who require a Two stage Revision Arthroplasty. A systemic antibiotic therapy should also be prescribed while the spacer remains implanted. The Knee Spacer is placed like a regular arthroplasty, after the removal of the original implant. This knee spacer consists of two independent parts: a tibial plate and a femoral component. The first has a flat base where the femoral component articulates. It is recommended that both components be adapted to the bone by means of a small amount of bone cement with antibiotic. The Knee Spacer must not remain implanted more than 6 months. Once this period has elapsed, it must be explanted and a permanent device implanted or another appropriate treatment performed.

The Shoulder Spacer with gentamicin preserves joint space and length of the affected limb, resulting in maintenance of the entire shoulder muscle and stabilizer complex. Its use is indicated for a limited period, in patients who require a Two-stage Revision Arthroplasty. A systemic antibiotic therapy should also be prescribed while the spacer remains implanted. The Shoulder Spacer is placed as a hemiarthroplasty after the original implant has been removed. The spacer is inserted into the humeral canal and a ring of bone cement with antibiotic can be added to the base of the neck of the spacer for added stability. The Shoulder Spacer should not remain in place for more than 6 months. Once this period has elapsed, it must be explanted and a permanent device implanted or another appropriate treatment performed.

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:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

510(k) Summary

Applicant information:

Company Name: Biocomposites Ltd.
Street Address: Keele Science Park
City: Keele
State / Province: Staffordshire
ZIP/Postal Code: ST5 5NL
Country: England

Contact information:

Contact name: Melisa Lamanna
Contact Title: Research and Development Manager
Phone Number: +54 (11) 5272 4060
Contact Email Address: mlamanna@subiton.com

Date Prepared: June 9, 2025
Proprietary Name: Synicem Hip, Knee, and Shoulder Spacers
Common Name: Temporary Hip, Knee, and Shoulder Spacers with Gentamicin
Proposed Class: II
Classification Name: Prosthesis, hip, hemi-, femoral, metal;
Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented;
Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer/metal/polymer;
Prosthesis, shoulder, hemi-, humeral, metallic uncemented or cemented.
Regulation Number: 21 CFR §888.3360, §888.3560, §888.3690
Product Codes: KWL, KWY, JWH, HSD, KWS

Predicate Device(s):

- Spacer-G, Temporary Hip Spacer with Gentamicin (K031841, K062273 and K101356).
- Spacer-K, Temporary Knee Spacer with Gentamicin (K032522, K062274 and K101356).
- Spacer-S, Temporary Shoulder Spacer with Gentamicin (K060535 and K112983).

Device Description:

The Synicem Hip, Knee, and Shoulder Spacers are combination products made from fully formed polymethylmethacrylate (bone cement) with gentamicin. The bone cement is prepared from a powder component and a liquid component. The hip and shoulder spacers contain a stainless-steel core of AISI 316L in accordance with ASTM F138. The spacers are temporary implants utilized to maintain the joint space during two-stage revision arthroplasties. The spacer implant is placed as part of the first stage of the two-stage revision when the original prostheses are removed due to joint infection. Once the infection is cleared, the spacers are removed and replaced with a permanent prosthesis as part of the second stage of the revision process. The joint spacers are not intended to be implanted for longer than 6 months. They are a single use device and supplied sterile.

Indications for Use:

Hip Spacers
INDICATIONS:
The Hip Spacer with gentamicin preserves the joint space and the length of the affected limb, which results in the maintenance of the entire abductor and stabilizer apparatus of the hip. Its use is indicated for a limited period, in patients who require a two-stage Revision Arthroplasty. A systemic antibiotic therapy should also be prescribed while the spacer remains implanted. The Hip Spacer is implanted after the removal of the infected implant, as a regular Hemiarthroplasty. The spacer is inserted into the femoral canal, and a handmade ring of PMMA bone cement with antibiotic may be added to the base of the spacer's neck in order to increase stability. The spacer is kept "in place" until it is replaced by the final prosthesis according to medical criteria. The Hip Spacer must not remain implanted for more than 6 months. Once this period has elapsed, it must be explanted and a permanent device implanted or another appropriate treatment performed.

Knee spacers
INDICATIONS:
The Knee Spacer with gentamicin maintains the articular space, the length of the affected limb, and the ligament apparatus of the knee. Its use is indicated for a limited period, in patients who require a Two stage Revision Arthroplasty. A systemic antibiotic therapy should also be prescribed while the spacer remains implanted. The Knee Spacer is placed like a regular arthroplasty, after the removal of the original implant. This knee spacer consists of two independent parts: a tibial plate and a femoral component. The first has a flat base where the femoral component articulates. It is recommended that both components be adapted to the bone by means of a small amount of bone cement with antibiotic. The Knee Spacer must not remain implanted more than 6 months. Once this period has elapsed, it must be explanted and a permanent device implanted or another appropriate treatment performed.

Shoulder spacers
INDICATIONS:
The Shoulder Spacer with gentamicin preserves joint space and length of the affected limb, resulting in maintenance of the entire shoulder muscle and stabilizer complex. Its use is indicated for a limited period, in patients who require a Two-stage Revision Arthroplasty. A systemic antibiotic therapy should also be prescribed while the spacer remains implanted. The Shoulder Spacer is placed as a hemiarthroplasty after the original implant has been removed. The spacer is inserted into the humeral canal and a ring of bone cement with antibiotic can be added to the base of the neck of the spacer for added stability. The Shoulder Spacer should not remain in place for more than 6 months. Once this period has elapsed, it must be explanted and a permanent device implanted or another appropriate treatment performed.

Technological Characteristics:

Device comparison demonstrated that Synicem Hip Spacer is substantially equivalent to the previously cleared Spacer-G (K031841, K062273 and K101356), Synicem Knee Spacer is substantially equivalent to the previously cleared Spacer-K (K032522, K062274 and K101356) and Synicem Shoulder Spacer is substantially equivalent to the previously cleared Spacer-S (K060535 and K112983), regarding intended use, indications for use, technological characteristics (design

features, material, sterilization and performance) as well as operating principle. The minor differences in design and size between the subject and the predicate devices do not raise any significant new risks. Through performance and mechanical testing it has been established that these differences do not present any new issues of safety or effectiveness.

	Subject Device	Predicate	Predicate	Predicate
510(k) Number	K242865	K031841, K062273, and K101356	K032522, K062274 and K101356	K060535 and K112983
Trade Name	Synicem Hip Spacer, Knee Spacer, and Shoulder Spacer	Spacer-G, Temporary Hip Spacer with Gentamicin	Spacer-K, Temporary Knee Spacer with Gentamicin	Spacer-S, Temporary Shoulder Spacer with Gentamicin
Regulation and Procode	21 CFR 888.3360 (Hip; KWL, KWY) 21 CFR 888.3560 (Knee; JWH) 21 CFR 888.3690 (Shoulder; HSD)	21 CFR 888.3360 (Hip; KWL, KWY)	21 CFR 888.3560 (Knee; JWH)	21 CFR 888.3690 (Shoulder; HSD)
Classification Name	Prosthesis, hip, hemi-, femoral, metal; Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented; Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer / metal / polymer; Prosthesis, shoulder, hemi-, humeral, metallic uncemented or cemented.	Prosthesis, hip, hemi-, femoral, metal; Prosthesis, hip, hemi-, femoral, metal/polymer, cemented or uncemented	Prosthesis, knee, patellofemorotibial, semi-constrained, cemented, polymer / metal / polymer	Prosthesis, shoulder, hemi-, humeral, metallic uncemented or cemented
Intended Use	Provide a temporary implant to allow for natural range of motion and partial weight bearing of the hip, knee, or shoulder. Preserve soft tissue structure	Provide a temporary implant to allow for natural range of motion and partial weight bearing of the hip. Preserve soft tissue structure	Provide a temporary implant to allow for natural range of motion and partial weight bearing of the knee. Preserve soft tissue structure	Provide a temporary implant to allow for natural range of motion and partial weight bearing of the shoulder. Preserve soft tissue structure

Material Composition	Gentamicin-impregnated PMMA spacer with stainless steel core	Gentamicin-impregnated PMMA spacer with stainless steel core	Gentamicin-impregnated PMMA spacer with stainless steel core	Gentamicin-impregnated PMMA spacer with stainless steel core
Sizes	Hip Head: 40, 48, 56 mm Stem: 120, 127, 130, 250 mm Knee Femoral: 58, 65, 72, 79 mm Tibia: 65, 73, 77.5, 85 mm Shoulder Head: 40, 48 mm Stem: 120 mm	Hip Head: 46, 54, 60 mm Stem: 96, 94, 98 mm	Knee Femoral: 54, 64, 74, 84 mm Tibia: 60, 70, 80, 90 mm	Shoulder Head: 41, 46 mm Stem: 99, 125 mm
Supplied Sterile	Yes	Yes	Yes	Yes

Performance Data

The Synicem Spacers have been evaluated through non-clinical performance testing.
The following mechanical testing was performed and results showed the Synicem Spacers were equivalent to the predicate spacers.

- Femoral stem and neck fatigue, and wear testing for the hip spacers.
- Fatigue performance and wear for the knee spacers.
- Static and dynamic fatigue testing for the shoulder spacers.

Antibiotic Elution Profile

Antibiotic Elution Kinetics testing was conducted to determine the antibiotic elution properties hip, knee, and shoulder subject´s spacers compared to the predicate spacers. These results demonstrate that the elution kinetics of the antibiotic in the subject hip, knee and shoulder spacers are equivalent to the elution kinetics of the antibiotic obtained for the predicate spacers.

Biocompatibility

Biocompatibility testing of Synicem Spacers was conducted in accordance with FDA guidance document, “Use of International Standard ISO 10993-1, “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process”.

- Cytotoxicity as per ISO 10993-5.
- Sensitization as per ISO 10993-10.
- Irritation as per ISO 10993-23.
- Acute systemic toxicity as per ISO 10993-11.
- Material-mediated pyrogenicity as per ISO 10993-11.
- Genotoxicity as per ISO 10993-3.

- Intramuscular implantation as per 10993-6.
- Local Effects after Bone Implantation / Subchronic Systemic Toxicity as per ISO 10993-6 and ISO 10993-11.

It has been demonstrated through the mentioned biological tests, the chemical characterization (ISO 10993-18) and the toxicological risk assessment (ISO 10993-17) that the materials of Synicem Spacers are biological safe, and suitable for their intended use.

MRI Safety

MR testing was conducted to FDA guidance document, Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment. The Synicem knee spacer is "MR Safe" and the Synicem Hip and Shoulder Spacers are "MR Conditional".

The testing demonstrated that the Synicem Spacers met performance requirements and is substantially equivalent to the predicate device.

Packaging, Sterilization and Shelf Life

Synicem Spacers are sterilized using well established sterilization methods and the validations have been performed following international standards and FDA guidance document "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile". The compatibility between the packaging material and the sterilization process is ensured and the packaging preserves the functionality and safety of Synicem Spacers throughout its declared shelf-life.

Substantial Equivalence:

The Synicem Spacers have the same indications for use and similar design features as compared with the predicate systems. The bench testing demonstrates that the performance characteristics of the Synicem Spacers are equivalent to those of the other legally marketed temporary spacer devices, and therefore supports a determination of Substantial Equivalence for the proposed indications for use. Any differences between the subject and predicate devices would not render the device NSE, affect the safety or effectiveness, or raise different questions of safety and effectiveness.