February 17, 2026

Biocomposites, Ltd.
% Scott Bruder
Founder and CEO
Bruder Consulting & Venture Group
38 True Harbour Way
West Islip, New York 11795

Re: K251680
Trade/Device Name: Biosteon® Screw
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: MAI, HWC
Dated: January 8, 2026
Received: January 13, 2026

Dear Scott Bruder:

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 Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 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 Management System Regulation (QMSR) (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,

CHRISTOPHER FERREIRA -S

Christopher Ferreira, M.S.
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

Please type in the marketing application/submission number, if it is known. This textbox will be left blank for original applications/submissions.	K251680

Please provide the device trade name(s).

Biosteon® Screw

Please provide your Indications for Use below.

The Biosteon™ Screw is indicated for use in anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL), lateral collateral ligament (LCL), and medial patellofemoral ligament (MPFL) reconstruction procedures where the surgeon:
• places the graft in tibial and/or femoral tunnels; and
• inserts between the tunnel wall and graft to hold the graft in place

The Biosteon™ Screw is used to provide interference fixation of patellar bone-tendon-bone grafts in ACL, PCL, MCL, LCL, and MPFL reconstruction.

The Bioston™ Screw is used to provide interference fixation during femoral and/or patellar tibial fixation in ACL, PCL, MCL, LCL, and MPFL reconstruction using a soft tissue graft (semi-tendonodesis gracilis).

Please select the types of uses (select one or both, as applicable).

- ☒ Prescription Use (Part 21 CFR 801 Subpart D)
- ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

510(k) Summary

Submitter
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201.874.9701

Date Prepared
May 30, 2025

Device

Trade Name	Biosteon® Screw
Common Name	Interference screw
Regulation	21 CFR 888.3030 Fastener, Fixation, Biodegradable, Soft Tissue
Classification	Class II
Product Code	MAI, HWC
Panel	Orthopedic

Predicates

Primary Predicate	Arthrex – FastThread Interference Screw (K202535)
Secondary Predicate	Biocomposites – Biosteon® Screw (K003641)
Reference Devices	Arthrex – SwiveLock Anchor (K201749)

Device Description
The Biosteon® Screw is a cannulated, tapered, sterile, single-use interference screw made of an absorbable polymer that will gradually be absorbed into the body. The Biosteon® Screw is manufactured from a mixture of hydroxyapatite (HA) and poly(L-lactide) (PLLA). The device is available in diameters 6mm - 12mm, and lengths 23mm -35mm.

Indications for Use Statement
The Biosteon™ Screw is indicated for use in anterior cruciate ligament (ACL), posterior cruciate ligament (PCL), medial collateral ligament (MCL), lateral collateral ligament (LCL), and medial patellofemoral ligament (MPFL) reconstruction procedures where the surgeon:

- places the graft in tibial and/or femoral tunnels; and
- inserts between the tunnel wall and graft to hold the graft in place

The Biosteon™ Screw is used to provide interference fixation of patellar bone-tendon-bone grafts in ACL, PCL, MCL, LCL, and MPFL reconstruction.

The Bioston™ Screw is used to provide interference fixation during femoral and/or patellar tibial fixation in ACL, PCL, MCL, LCL, and MPFL reconstruction using a soft tissue graft (semi-tendonodesis gracilis).

Substantial Equivalence

This submission expands the device's indications for use to include use in posterior cruciate ligament (PCL), medial collateral ligament (MCL), lateral collateral ligament (LCL), and medial patellofemoral ligament (MPFL). Compared to the original clearance (K003641), the subject device is tapered and has a smaller 6mm diameter option. Compared to the primary predicate, there are differences in the device's material composition and design (subject device is not vented), but this does not raise different questions of safety and effectiveness and is addressed with valid, scientific rationale.

Performance

The Biosteon interference screw has been previously cleared under K003641, which serves as a Secondary Predicate. This submission is leveraged to support the device's sterility, shelf-life, biocompatibility, and characterizations/bench performance. We provide new endotoxin testing and the device's performance in for the expanded indications was supported by additional mechanical testing on the smallest, worst-case device. Testing included insertion torque testing (0 weeks), cyclic pullout testing evaluating displacement (0 weeks), static pullout to failure testing (0, 6, and 12 weeks),and characterization including mass loss, number average molecular weight, weight average molecular weight, and polydispersity index (0, 6, and 12 weeks).

Summary

The subject device and predicates have the same intended use, and the same specific indications for use in the knee. Any differences in technological characteristics between the subject device and predicate do not raise different questions of safety and effectiveness. Biocomposites concludes that the device is substantially equivalent to the predicates.