December 6, 2024

Ames Medical Prosthetic Solutions, S.A.U.
Emili Tarrats
Plant Director
Ctra. Laurea Miro 388
Sant Feliu de Llobregat, Barcelona 08980
Spain

Re: K240461
Trade/Device Name: OsteoSinter® EVANS and COTTON wedges and related accessories
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: PLF
Dated: November 8, 2024
Received: November 8, 2024

Dear Emili Tarrats:

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,

Thomas Mcnamara -S

For: Christopher Ferreira, MS
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)*

K240461

Device Name

OsteoSinter® EVANS and COTTON wedges and related accessories

Indications for Use *(Describe)*

OsteoSinter® EVANS and COTTON wedges are intended to be used for internal bone fixation of bone fractures, fusions, or osteotomies in the foot. Specific Indications include:

- Opening wedge osteotomies of the bones of the foot (including osteotomies for Hallux Valgus).
- Opening wedge of Medial Cuneiform or Cotton osteotomies.
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy).
- Metatarsal/Cuneiform arthrodesis.

OsteoSinter® EVANS and COTTON wedges are indicated for use with ancillary bone fixation.
OsteoSinter® EVANS and COTTON wedges are not indicated for use in the spine

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:

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"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

DATE OF SUBMISSION: 2024-12-06
SUBMITTER NAME: AMES MEDICAL Prosthetic Solutions S.A.U.
SUBMITTER ADDRESS: Camí de Can Ubach 8, Pol. Ind. “Les Fallulles"
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SPAIN

CONTACT: Emili Tarrats
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DEVICE TRADE NAME: OsteoSinter® EVANS and COTTON wedges and related accessories
COMMON NAME: Bone Wedge
REGULATION DESCRIPTION: Single/Multiple component metallic bone fixation appliances and accessories
CLASS: Class II (Special Controls)
REGULATION NUMBER: 21 CFR 888.3030
PRODUCT CODE: PLF
REFERENCE PRODUCT CODE: HRS

PREDICATE DEVICE

K142724	BIOFOAM® Bone Wedge
K151256	Arthrex BioSync® Bone Wedge

DEVICE DESCRIPTION:
The OsteoSinter® EVANS and COTTON wedges are sterile, single use porous titanium implantable wedges, available in varied footprints and heights, intended to be used for correction of foot deformities.

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INTENDED USE / INDICATIONS FOR USE:

As established in the Indications for Use Statement:

OsteoSinter® EVANS and COTTON wedges are intended to be used for internal bone fixation of bone fractures, fusions, or osteotomies in the foot. Specific Indications include:

- Opening wedge osteotomies of the bones of the foot (including osteotomies for Hallux Valgus).
- Opening wedge of Medial Cuneiform or Cotton osteotomies.
- Lateral Column Lengthening (Evans Lengthening Osteotomy or Calcaneal Z Osteotomy).
- Metatarsal/Cuneiform arthrodesis.

OsteoSinter® EVANS and COTTON wedges are indicated for use with ancillary bone fixation.

OsteoSinter® EVANS and COTTON wedges are not indicated for use in the spine.

SUMMARY DISCUSSION OF NON-CLINICAL DATA:

The OsteoSinter® EVANS and COTTON wedges are substantially equivalent to the predicates devices (BIOFOAM® Bone Wedge, K142724 and Arthrex BioSync® Bone Wedge, K151256) in intended use/indications and in important physical and performance specifications. The subject and predicate device are substantially equivalent in design, features and material. The subject device was subjected to the following bench performance tests to support the assertion of substantial equivalence and evidence that no new safety or effectiveness concerns were raised:

- Static compressive strength
- Dynamic compressive strength
- Abrasion
- Friction

Biocompatibility testing, including chemical composition and animal testing, and in-vivo testing were also completed to support the equivalence of the subject device. The safety and effectiveness of OsteoSinter® EVANS and COTTON wedges is adequately supported by testing, substantial equivalence information, materials information and comparison of design characteristics provided within this premarket notification.

SUMMARY DISCUSSION OF CLINICAL DATA:

Non-clinical test data are submitted to support this premarket notification and to establish substantial

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equivalence. No clinical studies are submitted.

SUMMARY OF SUBSTANTIAL EQUIVALENCE DISCUSSION:

A comparison of the technological characteristic of the subject device with those of the predicate device is provided in the following table.

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Equivalent / similar device	Subject Device	Predicate Devices		Equivalence Discussion vs predicate device
		K142724	K151256	
	AMES Medical OsteoSinter® EVANS and COTTON wedges	WRIGHT BIOFOAM® Bone wedge	Arthrex BioSync® Bone Wedge	-
510(k)		K142724	K151256	-
Product Code	HRS	HRS; HWC	PLF, HRS, HWC	-
Class	Class II	Class II	Class II	Equivalent
Intended users	Health care professionals	Health care professionals	Health care professionals	Same
Contraindications	• Infection. •Physiologically or psychologically inadequate patient (conditions that tend to limit the patient's ability or willingness to restrict activities or follow post-operative care instructions). • Inadequate skin, bone or neurovascular conditions, which may delay healing. • Growing patients with open epiphyses. • Foreign body sensitivity. Where material sensitivity is suspected, testing is to be completed prior to device implantation.	• Infection • Physiologically or psychologically inadequate patient • Inadequate skin, bone, or neurovascular status • Irreparable tendon system • Possibility for conservative treatment • Growing patients with open epiphyses • Patients with high levels of activity	1. Insufficient quantity or quality of bone. 2. Blood supply limitations and previous infections, which may retard healing. 3. Foreign body sensitivity. Where material sensitivity is suspected, appropriate tests should	Equivalent

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	• Patient smoking may result in delayed healing, non-healing and/or compromised stability in or around the placement site.		be made and sensitivity ruled out prior to implantation. 4. Any active infection or blood supply limitations. 5. Conditions that tend to limit the patient's ability or willingness to restrict activities or follow directions during the healing period. 6. The use of this device may not be suitable for patients with insufficient or immature bone. The physician should carefully assess bone quality before performing orthopedic surgery on patients who are skeletally immature. The use of this medical device and the placement of hardware	

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			or implants must not bridge, disturb or disrupt the growth plate. 7. Do not use for surgeries other than those indi-cated.	
MRI Environments	Concerning Magnetic Resonance Environments; the devices have not been assessed for safety and compatibility in the Magnetic Resonance (MR) environment. The devices have not been tested for heating or migration in the MR environment.	Concerning Magnetic Resonance Environments The devices described in this package insert have not been evaluated for safety and compatibility in the MR environment. The devices described in this package insert have not been tested for heating or migration in the MR environment.	This device has not been evaluated for safety and compatibility in the magnetic resonance (MR) environment. This device has not been tested for heating, migration or image artifact in the MR environment. The safety of the device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury. If the implant is manufactured from a metallic material, surgeons can expect that MR artifacts will be present during routine MR imaging.	Equivalent

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Storage conditions	All implants and related accessories must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature and should not be used after the expiry date.	All implants must be stored in a clean, dry environment and be protected from sunlight and extremes in temperature.	This device must be stored in the original unopened packaging, away from moisture and should not be used after the expiration date.	Equivalent
	PHYSICAL AND MECHANICAL PROPERTIES			
Material	CP Titanium	CP Titanium	CP Titanium	Same
Total Porosity (%)	62-66	60-70	Average 58%	Same
Pore cell size averages (µm) *by SEM*	532,20±225	530 512,53±96,03	434-660	Equivalent
Average Interconnected pores diameter (µm)	270,36±96,29	200 192,45±45,73	229	Equivalent
Powder particle size (µm)	106-250	Not defined	Not defined	Similar
Apparent Elastic Modulus (GPa)	2,8	2,7	3,2	Equivalent
Compressive yield	31	86	Not defined	Similar

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Strength (MPa)				
Abrasion (% of weight loss at 1000 N)	0,32	13	0.2	Equivalent to K151256
Friction coefficient	1,22 ±0,28	0,58 ±0,02	1,07±0,10	Equivalent to K151256
Compressive fatigue limit	5M cycles exceed 11.3 MPa, without failure	Not defined	10M cycles exceed 10MPa, without failure	Equivalent to K151256
Technology	Powder metal sintering	Titanium deposition on open-cell scaffold	Diffusion bonding	Similar to K142724

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The subject and predicate device are substantially equivalent in design, features and material. Based on the non-clinical data provided in this submission, the technological characteristics of OsteoSinter® EVANS and COTTON wedges raise no new issues related to safety and effectiveness. Based on the information provided in this submission, OsteoSinter® EVANS and COTTON wedges are substantially equivalent to the predicates devices (K142724 and K151256).

CONCLUSIONS:

The design characteristics, material and intended use of the OsteoSinter® EVANS and COTTON wedges are substantially equivalent to the predicates devices BIOFOAM® Bone Wedge (K142724) and Arthrex BioSync® Bone Wedge (K151256). The safety and effectiveness of the OsteoSinter® EVANS and COTTON wedges are adequately supported by the substantial equivalence information, materials information and performance data provided within this Premarket Notifcation submission.