May 26, 2026

SDIP Innovations Pty Ltd
% Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA
Director, Regulatory Affairs
MCRA, LLC
803 7th Street NW, Floor 3
Washington, DC 20001

Re: K252797
Trade/Device Name: JAZBI™ Resorbable Bone Void Filler
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: April 17, 2026
Received: April 17, 2026

Dear Dr. Kazemzadeh-Narbat:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

JESSE MUIR -S

Digitally signed by JESSE MUIR -S
Date: 2026.05.26 09:14:19 -04'00'

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

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.	K252797

Please provide the device trade name(s).

JAZBI™ Resorbable Bone Void Filler

Please provide your Indications for Use below.

JAZBI™ Resorbable Bone Void Filler is indicated for use in bony voids or defects that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors (in adults), may be surgically created osseous defects, or osseous defects created by traumatic injury to the bone. JAZBI™ Resorbable Bone Void Filler is intended to be gently packed or placed into bony voids or defects of the extremities and pelvis. Following placement into the bony void, JAZBI™ Resorbable Bone Void Filler resorbs and is replaced with bone during the healing process.

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

Device Trade Name: JAZBI™ Resorbable Bone Void Filler

Submitter: SDIP Innovations Pty Ltd
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Date Prepared: May 22, 2026

Classifications: Filler, bone void, calcium compound

Class: Class II

Product Code: MQV

Primary Predicate: Synthes (USA) chronOS™ (K043045)

Indications For Use:

JAZBI™ Resorbable Bone Void Filler is indicated for use in bony voids or defects that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors, are surgically created or the result of traumatic injury to the bone. JAZBI™ Resorbable Bone Void Filler is intended to be gently packed or placed into bony voids or defects of the extremities and pelvis. Following placement into the bony void, JAZBI™ Resorbable Bone Void Filler resorbs and is replaced with bone during the healing process.

Device Description:

JAZBI™ Resorbable Bone Void Filler is composed of porous calcium phosphate in a polymeric matrix (poly(propylene carbonate) (PPC), and 3-Glycidyloxypropyltrimethoxysilane (GPTMS)). It is an osteoconductive, porous implant that allows for bony ingrowth across the graft site. The device is slowly resorbed and replaced by new bone tissue during the natural healing process. The bi-phasic calcium phosphate component of the device is made of beta-tricalcium phosphate and hydroxyapatite. The product is available in granules of different sizes and is provided sterile, non-pyrogenic, for single use only.

Performance Testing Summary:

Non-clinical data submitted to demonstrate substantial equivalence included:

- a scientific rationale for labeling the device as MR Safe
- sterilization gamma irradiation sterilization validation to a sterility assurance level of 10^{-6} by selecting and substantiating a 17.5 kGy dose according to ISO 13004, ISO 11137-1, and ISO 11137-2
- bacterial endotoxin testing including Limulus amebocyte lysate (LAL) test according to USP <85> to demonstrate that the sterile product meets a limit of $\leq$ 20 EU/device
- sterile barrier shelf-life testing of samples after accelerated aging to the equivalent of 24 months of real time aging according to ASTM F1980, with testing of the packaging sterile barrier according to ASTM F1886/F1886M, ASTM F1929, ASTM F88/F88M, and ASTM F2096
- subject device shelf-life testing of samples after real time aging to 18 months
- biocompatibility testing according to ISO 10993-5, ISO 10993-12, ISO 10993-10, ISO 10993-23, ISO 10993-11, ISO 10993-18, and a toxicological risk assessment according to ISO 10993-17
- the radiographic, histologic, and histomorphometric performance of the subject device were demonstrated to be equivalent to that of the primary predicate device K043045 in a rabbit critical-sized defect model

No clinical data were included in this submission.

Substantial Equivalence:

JAZBI™ Resorbable Bone Void Filler is substantially equivalent in technological characteristics including formulation, design, performance, route of administration, and intended use to the predicate Synthes (USA) chronOS™. The subject device and the primary predicate device are irregularly-shaped granules that incorporate similar calcium phosphate materials (a mixture of β-tricalcium phosphate and hydroxyapatite, or β-tricalcium phosphate only). The addition of polymeric binder constitutes of JAZBI™ Resorbable Bone Void Filler raises no new issues of safety or effectiveness as shown through the biocompatibility studies, the animal study in the critical-sized defect model, and the toxicological risk assessment. Performance data demonstrates that the subject device is substantially equivalent to the primary predicate device in K043045.

SUMMARY OF TECHNOLOGICAL SIMULARITIES AND DIFFERENCES

The subject device and the primary predicate device are irregularly-shaped granules that incorporate similar calcium phosphate materials (a mixture of β-tricalcium phosphate and hydroxyapatite, or β-tricalcium phosphate only). The subject device includes additional material of PPC and GPTMS as a portion of the material composition which is not present in the predicate device. The subject device and the primary predicate device are provided in the same ranges of granule sizes and are provided packaged in similar amounts as the primary predicate device. The subject device and the primary predicate device have similar porosity and similar ranges of pore sizes, and both are provided to the end user sterilized by gamma irradiation.

The radiographic, histologic, and histomorphometric performance of the subject device was compared to that of the primary predicate device in a rabbit critical-sized defect model study. The results of the study demonstrated the performance of the subject device was equivalent to that of the primary predicate device in the critical-sized defect model. Additionally, similar to the predicate device, the subject device successfully completed a biocompatibility and toxicological risk assessment per ISO 10993, proving that the subject device is safe to use as intended.

The similarities described, combined with animal performance testing and biocompatibility studies, support substantial equivalence of the subject device to the predicate device. The technological differences between the subject device and the primary predicate do not raise new questions of safety or effectiveness, and do not impact substantial equivalence.

Table 1: Summary of Substantial Equivalence

Device Characteristics	Subject Device **JAZBI™ Resorbable Bone Void Filler SDIP Innovations Pty Ltd**	Primary Predicate Device **Synthes (USA) chronOS™ Synthes (USA)**	Comparison with the Primary Predicate
510(k) Number	K252792	K043045	N/A
Common Name	Filler, Bone Void, Calcium Compound	Filler, Bone Void, Calcium Compound	Same
Regulation Information	21 CFR § 888.3045 Class II	21 CFR § 888.3045 Class II	Same
Product Code	MQV	MQV, FMF	Same
Intended Use	Bone void filler for use in the skeletal system: Extremities and pelvis	Bone void filler for use in the skeletal system: Extremities, pelvis, posterolateral spine	Same

Device Characteristics	Subject Device JAZBI™ Resorbable Bone Void Filler SDIP Innovations Pty Ltd	Primary Predicate Device Synthes (USA) chronOS™ Synthes (USA)	Comparison with the Primary Predicate
Indications for Use	JAZBI™ Resorbable Bone Void Filler is indicated for use in bony voids or defects that are not intrinsic to the stability of the bony structure. These osseous defects may be the result of benign bone cysts and tumors, are surgically created or the result of traumatic injury to the bone. JAZBI™ Resorbable Bone Void Filler is intended to be gently packed or placed into bony voids or defects of the extremities and pelvis. Following placement into the bony void, JAZBI™ Resorbable Bone Void Filler resorbs and is replaced with bone during the healing process.	Synthes chronOS™ is indicated for use in bony voids or gaps that are not intrinsic to the stability of the bony structure. Synthes chronOS™ is indicated for use in the treatment of bony defects created surgically or through traumatic injury. Synthes chronOS™ is intended to be gently packed or placed into bony voids or gaps of the skeletal system (i.e. the extremities, spine, and pelvis) and may be combined with autogenous blood and/or bone marrow. Following placement into the bony void, chronOS™ resorbs and is replaced with bone during the healing process.	Same
Mixing Prior to Use	Not indicated for mixing with autogenous blood, bone marrow, or allograft.	May be combined with autogenous blood and/or bone marrow.	Same
Form	Granules	Granules, blocks, wedges, cylinders	Same
Size	Granules 1.4-2.8 mm granules 2.8-5.6 mm granules	Granules 0.7-1.4 mm granules 1.4-2.8 mm granules 2.8-5.6 mm granules	Same
Porosity	Granules – 48.5%	Granules – 60%	Same
Pore Size	113 μm – 228 μm	100 μm – 500 μm	Same
Material	• Calcium phosphate – composed of β-tricalcium phosphate (TCP) and Hydroxyapatite (HA) • PPC • GPTMS	• β-tricalcium phosphate (TCP)	Differences do not raise new questions of safety and efficacy. Testing demonstrates that the differences do not adversely impact performance.
Sterility	Provided sterile to end user	Provided sterile to end user	Same
Sterilization	Gamma Irradiation	Gamma Irradiation	Same
Usage	Single patient, single use	Single patient, single use	Same

Conclusion:

JAZBI™ Resorbable Bone Void Filler and the predicate device has the same intended use, has similar technological characteristics, and are made of similar materials. The data included in this submission demonstrates substantial equivalence to the predicate device listed above. JAZBI™ Resorbable Bone Void Filler is as safe, as effective, and performs as well as the predicate device.