Molecular Matrix, Inc.
% Mr. John Kapitan
Chief Executive Officer
Kapstone Medical
P.O. Box 969
Leicester, North Carolina 28748

December 29, 2017

Re: K170165
Trade/Device Name: Osteo-P™ Bone Graft Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 27, 2017
Received: November 30, 2017

Dear Mr. Kapitan:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K170165

Device Name
Osteo-P™ Bone Graft Substitute

Indications for Use *(Describe)*

Osteo-P™ Bone Graft Substitute is indicated for use only in the treatment of bony voids or gaps that are not intrinsic to the stability of the bony structure. It is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis), and the opening to the defect site sealed with bone wax. These defects may be surgically created osseous defects or osseous defects created from traumatic or degenerative injury to the bone. Subsequent to implantation, Osteo-P™ Bone Graft Substitute is resorbed and replaced with bone during the healing process.

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.

510(k) Summary

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) summary for Osteo-P™ is provided below.

Date Summary Prepared:	November 17, 2017
Submitter Name:	Molecular Matrix, Inc.
Submitter Address:	3410 Industrial Blvd., Suite 103 West Sacramento, CA. 95691
Contact Person:	John Kapitan Kapstone Medical, LLC
Phone Number: ***Fax Number:***	916-374-9404 530-231-6126
Device Trade Name:	Osteo-P™ Bone Graft Substitute
Device Common Name:	Resorbable bone void filler
Classification Name: ***Classification Number:*** ***Product Code:***	Bone Void Filler Device 21 CFR 888.3045 MQV
Primary Predicate Device: ***Reference Device:***	K063359 ISTO Technologies, Inc. InQu® K043045 Synthes (USA) chronOS®

Device Description

Osteo-P™ Bone Graft Substitute is a radiolucent bone void filler composed of a porous, osteoconductive polymeric carbohydrate with a trabecular structure simulating the multi-dimensional interconnectivity of human cancellous bone. When placed in direct contact with host bone, Osteo-P™ supports and guides the ingrowth of new bone across the graft site and is resorbed as the healing process occurs. The consistency of Osteo-P™ allows the surgeon to easily manipulate and maximize the direct contact with viable host bone. It is intended for single patient use only and is provided sterile in single-use double sterile packaging. Osteo-P™ is available in various forms to include granules, sheets, cubes, wedges, and cylinders.

Indications for Use

Osteo-P™ Bone Graft Substitute is indicated for use only in the treatment of bony voids or gaps that are not intrinsic to the stability of the bony structure. It is intended to be gently packed into bony voids or gaps of the skeletal system (i.e., the extremities and pelvis), and the opening to the defect site sealed with bone wax. These defects may be surgically created osseous defects or osseous defects created from traumatic or degenerative injury to the bone. Subsequent to implantation, Osteo-P™ Bone Graft Substitute is resorbed and replaced with bone during the healing process.

Technological Characteristics

Testing has confirmed Osteo-P™ Bone Graft Substitute to be biocompatible as a bone void filler device. Animal testing demonstrated evidence of new bone formation consistent with FDA's recommendations for performance testing of Class II Bone Void Filler Devices. Osteo-P™ is substantially equivalent to the predicate device in terms of design, function, intended use and bone healing performance in an animal model. Results from a NZW Rabbit femoral condyle critical-sized defect study comparing Osteo-P™ to the predicate device and autograft as well as extensive biocompatibility testing demonstrated that the differences in raw material composition do not raise new issues of safety and effectiveness.

Substantial Equivalence

Characteristic	**Osteo-P™ Bone Graft Substitute (subject device)**	**InQu® Bone Graft Substitute (predicate device)**	**chronOS® Bone Void Filler (reference device)**	**Comparison**
510(k)		K063359	K013072	N/A
Intended Use	Resorbable Bone void Filler	Resorbable Bone void Filler	Resorbable Bone void Filler	Equivalent
Target Population	Individuals with bony defects resulting from surgery or trauma; not intrinsic to the stability of the structure	Individuals with bony defects resulting from surgery or trauma; not intrinsic to the stability of the structure	Individuals with bony defects resulting from surgery or trauma; not intrinsic to the stability of the structure	Equivalent
Anatomical Location	Bony voids or gaps of the skeletal system, (i.e., the extremities and pelvis)	Bony voids or gaps of the skeletal system, (i.e., the extremities and pelvis)	Bony voids or gaps of the skeletal system, (i.e., the extremities, spine and pelvis)	Equivalent to predicate device
Technological Characteristics				
Principle of Operation	Provide Osteoconductive Matrix	Provide Osteoconductive Matrix	Provide Osteoconductive Matrix	Equivalent
Material of Construction	Porous osteoconductive polymer matrix	Porous osteoconductive polymer matrix	Porous osteoconductive polymer matrix	Equivalent
Shapes	Variety (to include): Granules, Sheets, Cubes, Wedges, and Cylinders	Variety: Granules and Sheets	Variety (to include): Granules, Blocks, Wedges, and Cylinders	Equivalent to reference device
Sizes	Granules: 1-5mm Preformed shapes: Variety	Granules: 2-5mm Sheets: Variety	Granules: 1.4mm-2.8mm & 2.8mm-5.6mm. Preformed shapes: Variety	Equivalent

Porosity	75-95%	75-90%	60-70%	Equivalent to predicate device
Pore Size	~1-700 µm main distribution: 50-500 µm	~1-300µm	Macropores: 100-500µm (main distribution) Micropores: <10 µm	Equivalent
Radiolucency	Radiolucent	Radiolucent	Radiopaque	Equivalent to predicate device
Performance				
Surgical Application Restrictions/Use	Gently packed into defect. Requires appropriate fixation/stabilization. Requires hydration	Gently packed into defect. Requires appropriate fixation/stabilization. Requires hydration.	Gently packed into defect. Requires appropriate fixation/stabilization. Requires hydration	Equivalent
Osteoconductivity	Osteoconductive	Osteoconductive	Osteoconductive	Equivalent
Resorbable	Yes	Yes	Yes	Equivalent
Mechanical Strength	Does not impart mechanical strength to surgical site.	Does not impart mechanical strength to surgical site.	Compressive strength ~5MPa	Equivalent to predicate device
Packaging	Double sterile pack.	Double sterile pack	Double sterile pack.	Equivalent
Sterility	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Sterile, SAL 10^{-6}	Equivalent
Sterilization Method	E-Beam	E-Beam	E-Beam	Equivalent
Pyrogenicity	Non-pyrogenic Limulus Amebocyte Lysate (LAL) Chromogenic Endotoxin Quantitation Assay	Non-pyrogenic	Non-pyrogenic	Equivalent
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Equivalent

The following technological differences exist between the subject and predicate or reference devices:

Characteristic	Osteo-P™ (subject device)	InQu® (predicate device)	chronOS® (reference device)
Material Composition	Porous Hyper Cross-linked Polymeric Carbohydrate	Porous PGLA / HA matrix	Porous β-Tricalcium Phosphate (TCP)

Pre-Clinical Testing confirmed that despite differences in material composition, Osteo-P™ is equivalent to the predicate device in function, indication for use, device classification product code, environment of use, and principles of operation to the predicate device. The biocompatibility of Osteo-P™ has also been confirmed through extensive *in vitro* and *in vivo* testing.