April 21, 2021

Biostone Limited
Wei-Jen Lo, Ph.D.
Chief Scientific Officer
BioCity, Pennyfoot Street
Nottingham, Notts NG1 1GF
United Kingdom

Re: K202639
Trade/Device Name: si-Mochi
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: March 16, 2021
Received: March 29, 2021

Dear Dr. Lo:

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. 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 located 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.

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) for devices or postmarketing safety reporting (21 CFR 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 4, Subpart A) for combination products; 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 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,

for

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K202639

Device Name

si-Mochi

Indications for Use *(Describe)*

si-Mochi is an implant intended to fill bony voids or gaps of the skeletal system (i.e.extremities, pelvis). These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. si-Mochi resorbs and is 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.

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Submitter	Biostone Limited BioCity Pennyfoot Street Nottingham NG1 1GF United Kingdom
Telephone	011 44 7906 001281
Facsimilie	
Contact Person	Wei-Jen Lo PhD
Date Prepared	21/ July/ 2019
Trade Name	si-Mochi
Common Name	Resorbable calcium salt bone void filler device
Classification	Resorbable calcium salt bone void filler devices have been classified by the Orthopedics Device Panel as Class II Special Controls per 21 CFR 888.3045. Product code: MQV
Predicate Devices	TriPore® K070132, Actifuse ABX™ K082575
Device Description	si-Mochi contains a multi porous bi-phase Calaium Phosphate ceramic granules, 1~2mm, suspended in an aqueous polymer carrier gel. The chemical composition of the multi-porous ceramic granules is trace silicate induced bi-phase calcium phosphate ceramic which has 80% hydroxylapatite $Ca_5(PO_4)_3(OH)$ and 20% β-tricalcium phosphate $Ca_3(PO_4)_2$, similar levels to those identified in naturally-growing bone. Its porous structure comprising three types of porosities which are interconnected: macropores (100μm~1mm), midipores (10~100 μm) and microspaces (1~10 μm). Calcium phosphate bone graft substitutes have been the topic of extensive clinical studies for several decades. Biocompatibility is addressed in the non-clinical testing section below.The interconnected macro-, midi- and micro- porous structure encourages the rapid formation of host bone and the growth of capillary blood vessels throughout the network of interconnecting pores. After implantation, si-Mochi undergoes physiologically-mediated resorption and is replaced by natural bone.

	The resorption of the Ca/P porous ceramic granules were controlled by the host nature bone remodelling process due to the proliferated osteocytes formation within the microporous structure of the ceramic granules. The resorption is not controlled by its chemical composition. si-Mochi is supplied in three different types of sterile applicator. si-Mochi does not set in-situ following implantation. si-Mochi does not contain antibiotics.

Intended Use	si-Mochi is an implant intended to fill bony voids or gaps of the skeletal system (i.e. extremities, pelvis). These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. si-Mochi resorbs and is replaced with bone during the healing process.
Technical Characteristics and Substantial Equivalence	si-Mochi and the predicate device, Actifuse ABX share similar characteristics in that they are all calcium salt bone void fillers covered by 'Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device" (FDA Guidance Document 855, dated June 2, 2003). Both si-Mochi and Actifuse ABX are packed in different type of applicator for different clinic application. Both have the multi-porous Ca/P ceramic granules with added trace silicate, 1~2mm, suspended in the same chemical composition of synthetic aqueous binding gel. The multi-porous ceramic granules in si-Mochi are near identical to TriPore SBG. They share the same chemical composition but the multiparous Ca/P ceramic granules had added additional trace silicate. They have the same multi-porous structure and their manufacturing process and annealing profile are exactly the same.
Determination of substantial equivalence	Biostone has determined that si-Mochi is substantially equivalent to the predicate devices on the basis of

(non-clinical data)	chemical composition tests on all three devices as prescribed in the 'Class II Special Controls Guidance Document' referenced above. Secondly, si-Mochi itself complies with the requirements of the Special Controls Document referred to above. The non-clinical data also included biocompatibility, pyrogenicity testing and endotoxin monitoring, shelf-life and packaging validation.
Determination of substantial equivalence (animal studies)	Animal study, rabbit critical size defect in the distal femora model, making direct comparison against the predicate device, Actifuse ABX. However, the percentage of new bone formations were not statistically significant difference in animal model at all time points post-implantation between si-Mochi and the predicate device.
Technical Characteristics Difference	si-Mochi and Actifuse ABX 1) The first is the chemical composition, where the calcium phosphate granules in Actifuse ABX is pure hydroxylapatite with 0.8% Silicate. The calcium phosphate granules in si-Mochi comes as bi-phase calcium phosphate comprised of 20% beta tri-calcium phosphate and 80% hydroxylapatite with 0.8% silicate. The differences in the chemical composition of the porous calcium phosphate ceramic granules do not affect the safety or effectiveness of si-Mochi, since all materials are resorbable and provide the same function. 2) The second is the viscosity of the Kolliphor gel in both si-Mochi and Actifuse ABX. The composition of Kolliphor gel in the Actifuse ABX is at 20%, and the viscosity will increase when the temperature raised to human body temperature at 37^{o}C. However, it was found that the low viscosity gel is not sufficient to hold the granules together during the lower operation theater temperature. Therefore, the composition of the Kolliphor gel was increased to 33% to construct si-Mochi, for si-Mochi to function normally in operation theater condition. The Kolliphor gel is bioinert and will not impede the function of the porous calcium phosphate ceramic granules as the bone ingrowth scaffold. si-Mochi and Tripore The only difference is that the porous Ca/P ceramic granules contain additional 0.8% of Silica in its chemical composition, the same as the other predicate device Actifuse ABX. However, the added Silica shall not affect its clinical performance. Since the osteointegration thesis of the porous ceramic granules and TriPore® are precisely the same. These differences do not raise new issues of safety.

Conclusions	Therefore, Biostone concludes that the non-clinical and animal studies discussed above demonstrate that si-Mochi performs as well the predicate device.