Wiltrom Corporation Limited
Yi-Chun Su
Director
1F, No. 26, Section 2, Shengyi Road
Zhubei City, Hsinchu County 30261
Taiwan (Republic of China)

February 2, 2018

Re: K172237
Trade/Device Name: Bicera® Resorbable Bone Substitute
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: December 29, 2017
Received: January 2, 2018

Dear Yi-Chun Su:

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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K172237

Device Name

Bicera® Resorbable Bone Substitute

Indications for Use *(Describe)*

Bicera® Resorbable Bone Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Bicera® Resorbable Bone Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. Bicera® Resorbable Bone Substitute is intended to be packed into bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis) as a bone void filler. This product provides a bone void filler that resorbs and is replaced by 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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510(k) Summary

Submitter

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Date Prepared

Sep 6, 2017

Trade Name

Bicera® Resorbable Bone Substitute

Common Name

Bone Void Filler

Device Classification

Class II, 21 CFR §888.3045
Resorbable Calcium Salt Bone Void Filler Device

Product Code / Panel

MQV / Orthopedic

Predicate Devices

Bicera™ Resorbable Bone Substitute (K110949)
MBCP™ Bone Graft Substitute (K032268)

Relevant Guidance Document

Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device

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Device Description

Bicera® Resorbable Bone Substitute is a bioceramic medical device that its composition of crystalline phase contains 60% hydroxyapatite (HAP) and 40% beta-tricalcium (ß-TCP). The bone graft can be used as a bone filler for orthopedic surgery. It is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. The composite material is gradually resorbed and replaced by bone tissues. Bicera® Resorbable Bone Substitute is supplied sterile in various shapes and sizes.

Intended Use

Bicera® Resorbable Bone Substitute is intended for use as a bone void filler for voids or gaps that are not intrinsic to the stability of the bony structure. Bicera® Resorbable Bone Substitute is indicated for use in the treatment of surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. Bicera® Resorbable Bone Substitute is intended to be packed into bony voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis) as a bone void filler. This product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Comparison of Technological Characteristics

The Bicera® Resorbable Bone Substitute and the predicate devices are resorbable calcium salt bone void filler consisting 60% HAP and 40% ß-TCP. The physiochemical properties (e.g., interconnected porous structure, pore size distribution, porosity, Ca/P ratio, etc.) of Bicera® are similar to the predicate devices.

Discussions of Non-Clinical Tests for Determination of Substantial Equivalence

Physical and chemical properties evaluations, biocompatibility tests and functional animal studies were performed for Bicera® Resorbable Bone Substitute. Biocompatibility of the device has been established according to ISO 10993 and relevant standards. Test results of cytotoxicity, sensitization, irritation, subchronic toxicity, acute systemic toxicity and genotoxicity assessments are considered acceptable. The subcutaneous implantation study shows that Bicera® has a good affinity with the surrounding tissue and elicits no inflammation or adverse reaction. The pyrogen and endotoxin testing indicate that Bicera® meets the pyrogen limit specifications. In addition to these biocompatibility assessments, the comparison of Bicera® to the predicate device in the implantation in long bone animal model and posterolateral spine fusion model demonstrate that Bicera® has similar effectiveness in bone formation to the predicate device.

Conclusion

The purpose of this submission is to expand the indications for use of the originally cleared Bicera™ Resorbable Bone Substitute (K110949). The subject device is identical

to the device described in K110949. Bicera® Resorbable Bone Substitute has the same intended use and similar indications, technological characteristics and principles of operation to the predicate device, MBCP™ (K032268). Based on the non-clinical testing data, Bicera® is determined substantially equivalent to the predicate devices.