October 24, 2018

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

Re: K180758
Trade/Device Name: Osteocera 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: September 14, 2018
Received: September 17, 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. 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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

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,

Laurence D. Coyne -S

For 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)*
K180758

Device Name

Osteocera Resorbable Bone Substitute

Indications for Use *(Describe)*
Osteocera Resorbable Bone Substitute is intended for use as a bone void filler for voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis) that are not intrinsic to the stability of the bony structure. Osteocera Resorbable Bone Substitute is indicated for use in the treatment of osseous defects created surgically or through traumatic injury. Following placement into the bony void, Osteocera Resorbable Bone Substitute 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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) Summary

I.	**Submitter**	Wiltrom Corporation Limited No. 221, Sec. 1, Chung Hsing Rd. Chutung, Hsinchu County 31053 Taiwan
	Contact Information	Yi-Chun Su, Director 1F, No. 26, Sec. 2, Shengyi Rd. Zhubei City, Hsinchu County 30261 Taiwan TEL: +886-3-6107168 FAX: +886-3-6580006
	Date Prepared	March 12, 2018
II.	**Subject Device**	Osteocera Resorbable Bone Substitute
	Common Name	Bone Void Filler
	Classification Name	Resorbable Calcium Salt Bone Void Filler Device
	Regulation Number	21 CFR §888.3045
	Product Code / Device Class	MQV / Class II
	510(k) Review Panel	Orthopedic
III.	**Predicate Device**	Synthes (USA) chronOS (K043045)

IV. Device Description

Osteocera Resorbable Bone Substitute is a bioceramic medical device that consists of over 95% beta-tricalcium phosphate (ß-TCP). Osteocera is a resorbable implant intended to fill bony voids or gaps that are caused by trauma or surgery and are not intrinsic to the skeletal stability. The interconnected porous structure of Osteocera provides a matrix for bone ingrowth. Osteocera Resorbable Bone Substitute is for single use only and is supplied sterile in sticks and granules with various sizes and package volumes.

V. Indication for Use

Osteocera Resorbable Bone Substitute is intended for use as a bone void filler for voids or gaps of the skeletal system (i.e., extremities, posterolateral spine and pelvis) that are not intrinsic to the stability of the bony structure. Osteocera Resorbable Bone Substitute is indicated for use in the treatment of osseous defects created surgically or through traumatic injury. Following placement into the bony void, Osteocera Resorbable Bone Substitute resorbs and is replaced with bone during the healing process.

VI. Comparison of Technological Characteristics with the Predicate Device

The subject device has the same intended use and technological principles as the predicate device. The devices are both ß-TCP bone substitutes with porous structure. The interconnected pores provide a scaffold for bone ingrowth, and the biodegradable ß-TCP allows replacement of the bone substitute by natural bone. The subject device has higher porosity and similar pore size distribution to that of the predicate device. The devices are to be used in non-load bearing indications and internal fixation techniques may often be recommended to stabilize the operating area. Both devices are biocompatible and are sterilized by irradiation.

	Subject Device	**Predicate Device**
Trade Name	Osteocera Resorbable Bone Substitute	Synthes (USA) chronOS (K043045)
Intended Use	To be used as bone void filler and to provide a matrix for bone ingrowth	To be used as bone void filler and to provide a matrix for bone ingrowth
Anatomical Site	Bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis)	Bony voids or gaps of the skeletal system (i.e. the extremities, spine and pelvis)
Indications for Use	▪ Bony voids or gaps that are not intrinsic to the stability of the bony structure ▪ Bony defects created surgically or through traumatic injury	▪ Bony voids or gaps that are not intrinsic to the stability of the bony structure ▪ Bony defects created surgically or through traumatic injury
Composition	β-TCP conforming to ASTM F1088	β-TCP conforming to ASTM F1088
Design	▪ Biodegradable ceramic ▪ Interconnected porous structure	▪ Biodegradable ceramic ▪ Interconnected porous structure
Performance	▪ Possessing osteoconductivity to promote bone formation ▪ Resorbing and being replaced with bone during the healing process	▪ Possessing osteoconductivity to promote bone formation ▪ Resorbing and being replaced with bone during the healing process
Porosity	75-85%	60-70%
Pore Size	300-600 µm	100-500 µm
Physical Form	Stick, granules	Blocks, wedges, granules and cylinders
Dimension	<u>Stick</u> ▪ 5 x 5 x 10 mm ▪ 5 x 5 x 20 mm <u>Granules</u> ▪ 0.25-0.5 mm ▪ 0.5-1.0 mm ▪ 1.0-2.0 mm ▪ 2.0-3.0 mm	<u>Block</u> ▪ 5 x 5 x 10 mm ▪ 12.5 x 12.5 x 10 mm ▪ 20 x 20 x 10 mm <u>Granules</u> ▪ 0.5-0.7 mm ▪ 0.7-1.4 mm ▪ 1.4-2.8 mm ▪ 2.8-5.6 mm
Biocompatibility	Established	Established
Sterility	Sterile (SAL:10^{-6})	Sterile (SAL:10^{-6})
Sterilization	Gamma irradiation	Gamma irradiation

VII. Performance Data

The following performance data were provided in support of the substantial equivalence.

Biocompatibility testing

ISO 10993 standards and the FDA guidance "*Use of International Standard ISO 10993-1, 'Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process'* " were applied to evaluate the biocompatibility of Osteocera Resorbable Bone Substitute. Osteocera is considered biologically safe based on the device characterization and biocompatibility testing data regarding cytotoxicity, sensitization, irritation, acute systemic toxicity, subchronic toxicity, genotoxicity, pyrogenicity and hemocompatibility.

Animal testing

The performance of Osteocera in the extremities and posterolateral spine indications was studied in the distal femur and the posterolateral spine of New Zealand white rabbit, respectively. Skeletally matured animals were used in these studies. Evaluation was carried out at three time points: 4, 12 and 24 weeks post-implantation. In the distal femur implantation study, critical sized defects were created in 18 animals. Radiographic, histological, and histomorphometric analyses were performed at each time point to observe implant resorption and new bone formation over time. In the posterolateral spine study, bone grafts were placed between the transverse processes in the paraspinal bed of 36 animals. Manual palpation, posteroanterior radiographic, histological and histomorphometric data were collected. The animal studies demonstrated that Osteocera is as safe and effective as the predicate device in the indications.

VIII. Conclusion

Osteocera Resorbable Bone Substitute has the same intended use and indications for use as the predicate device, Synthes (USA) chronOS (K043045). Based on the material, technological characteristics and non-clinical data, Osteocera Resorbable Bone Substitute is substantially equivalent to the predicate device.