510(K) Summary

SEP 18 2012

1. Submitter's Identification

Address: No.221, Sec.1, Chung Hsing Rd., Chutung, Hsinchu, Taiwian 31053, R.O.C.
TEL: (886) 3-582-8999
FAX: (886) 3-582-6859
Contact: Yung-Chih Wu

US Representative:

Address: 5025 Collwood Way, Unit 19 San Diego, CA 92115, USA
TEL: 1-808-277-1579
Email: mhanb20012001@gmail.com
Contact: Yi-An Lai

2. Proprietary Name

Bicera™ Resorbable Bone Substitute

3. Common Name

Bone Void Filler

4. Classification Name

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

5. Device Code/Panel Code

Orthopedics/MQV

6. Predicate Device

MBCP™ Bone Graft Substitute, K032268

7. Mandatory Performance Standard

Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA (Document # 855)

8. Voluntary Performance Standards

ISO 11137-2:2006
ISO 9001:2000
ISO 10993-1,3,5,6,10,11,12,14
ISO/IEC 17025:2005
21 CFR 58
ASTM F2150-02
ASTM D695-02a
ASTM D1621-04a
ASTM D3576-4
ASTM F1185-03
ASTM F1185-87
ASTM D4332
ASTM F1140-07
ASTM F88-07a
ASTM F1929-98
ASTM F1608-00
ASTM F895
ASTM F1408-97
ASTM F1980-07

9. 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 (B-TCP). Bicera™ is a bone void 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. This composite material is resorbed slowly in vivo and is replaced by new bone. Bicera™ Resorbable Bone Substitute is supplied sterile in various shapes and sizes. See Table 1 below for

available shapes and sizes.

Table 1. Product Form

Form	Size
Stick, ≦ 5 mm width or height ≦ 20 mm length	2.0 to 10.0 cm^3 total volume
Granule, ≦ 3 mm diameter	0.25, 0.5, and 1 gram

10. 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 as a bone void filler (*i.e.*, extremities and pelvis). This product provides a bone void filler that resorbs and is replaced by bone during the healing process.

11. Comparison to Predicate Device

Bicera™ is substantially equivalent in design, function, and intended use to MBCP™ Bone Graft Substitute cleared as K032268 on December 11, 2003.

Comparison of Technological Characteristics between Bicera™ and MBCP™

	Bicera™	MBCP™
Composition (wt%)	60% HAP and 40% β-TCP	60% HAP and 40% β-TCP
Porosity (%)	79.22 ± 1.04	70
Pore size (μm)	442.65 ± 80.31	450 ± 49
Ca/P	1.61	1.60 ± 0.02
Density (g/cm^3)	0.64 ± 0.03	0.87 ± 0.04
Pore structure	Interconnected pores	Interconnected pores
Specific surface area (m^2/g)	1.57	1.8 ± 0.1
Compressive strength (MPa)	1.80 ± 0.24	3.04 ± 0.79

12. Discussions of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows

Assessments for biocompatibility evaluation are based on the final, to-be-implanted version of Bicera™. These assessments were conducted in accordance with the International Standard ISO 10993 part 4, 5, 6, 10, 11, ASTM F-1408-97, USP <85> version 34, <161> version 34 and the guideline provided by the FDA of the United

States. The test results for cytotoxicity, sensitization, irritation, acute systemic toxicity, and pyrogen assessments were considered acceptable. The result of the subcutaneous implantation study shows that Bicera™ has a good affinity with the surrounding tissue with no observations of inflammatory or adverse reaction. It can be concluded that Bicera™ has a substantially equivalent biocompatibility to that of MBCP™. Bicera™ is mainly composed of 60% of hydroxyapatite and 40% of β-tri-calcium phosphate which is an osteoconductive material and has been widely applied in clinical application for years. In addition to these biocompatibility assessments, Bicera™ was compared to the predicate device in a long bone animal critical sized defect model. The results over time at multiple post-op evaluations demonstrate that Bicera™ was substantially equivalent to the predicate device with respect to resorption profile and new bone formation.

13. Discussion of Clinical Tests Performed

N/A

14. Conclusion

We have demonstrated that the Bicera™ is substantially equivalent to the predicate device,MBCP™ (K032268), based on physical and chemical characteristics as well as biocompatibility and animal implantation testing.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Wiltrom Corporation Limited
% Mr. Yung-Chih Wu
Plant Manager
No. 221, Section 1, Chung Hsing Road
Chutung Township, Hsinchu
China (Taiwan) 31053

SEP 1 8 2012

Re: K110949
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: August 27, 2012
Received: August 28, 2012

Dear Mr. Wu:

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.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE

510(k) Number (if known): K110949

Device Name: Bicera™ Resorbable Bone Substitute

Indications For 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 as a bone void filler (*i.e.*, extremities and pelvis). This product provides a bone void filler that resorbs and is replaced by bone during the healing process.

Prescription Use X AND/OR Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K110949