HUDENS BIO Co., Ltd.
% Mikael Hellstrand
RA Manager
K-Bio Solutions
Suite 701,125 Seochojungang-ro, Seocho-gu
Seoul, 06644
KOREA, SOUTH

March 06, 2026

Re: K251818
Trade/Device Name: Bontree Plus
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: February 4, 2026
Received: February 6, 2026

Dear Mikael Hellstrand:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13484 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental 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)*
K251818

Device Name
BONTREE PLUS

Indications for Use *(Describe)*
BONTREE PLUS is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/ maxillofacial defects, including
- Periodontal/infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Sinus lifts
- Cystic cavities

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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The assigned 510(k) Number: K251818

510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirement of 21 CFR 807.92.

1. Submitter's Information

- Sponsor Name: HUDENS BIO Co., Ltd.
- Address: 318 Cheomdanyeonsin-ro, Buk-gu, Gwangju, Republic of Korea
- Postal Code: 61088

Application Consulting Correspondent:

- Contact Person: Mr. Kyungyoon Kang
- Company: KBIO Solutions
- Address: 125 Seochojungang-ro, Seocho-gu, Seoul, Republic of Korea
- Tel: USA: 408-750-7843, KOR: +82-10-3648-7021
- E-mail: kyungyoon.kang@kbiotechsolutions.com

2. Date of the summary prepared: March 6, 2026

3. Subject Device Information

- Type of 510(k): Traditional
- Trade Name: BONTREE PLUS
- Classification Name: Bone grafting material, Synthetic
- Review Panel: Dental
- Product Code: LYC
- Regulation: 21 CFR 872.3930
- Regulatory Class: Class II

4. Predicate Device Information

- Sponsor: GENOSS Co., Ltd.
- Trade Name: OSTEON II
- Classification Name: Bone grafting material, Synthetic
- 510(k) Number: K112716
- Product Code: LYC
- Regulation Number: 21 CFR 872.3930
- Regulation Class: Class II

5. Reference Device Information

- Sponsor: Tissue Regeneration Systems, Inc.
- Trade Name: TRS PCL Cranial Bone Void Filler
- Classification Name: Burr Hole Cover
- 510(k) Number: K123633
- Product Code: GXR
- Regulation Number: 21 CFR 882.5250
- Regulation Class: Class II

6. Device Description

BONTREE PLUS is a synthetic bone graft substitute composed of hydroxyapatite (HA) and octacalcium phosphate (OCP). BONTREE PLUS is available in granule type ranging in weight (g)/volume (cc) from 0.15g/0.3cc to 1.0g/2.0cc, and particle size ranges from 0.3mm to 1.4mm. BONTREE PLUS is supplied in vials as a single-use, prescription-only, sterile device (sterilization by gamma radiation).

7. Indications for Use

BONTREE PLUS is intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects, including
- Periodontal/infrabony defects
- Ridge augmentation
- Extraction sites (implant preparation/placement)
- Sinus lifts
- Cystic cavities

8. Comparison to Predicate Device and Reference Device

The differences between the subject device, predicate device, and reference device do not raise new issues of safety or effectiveness.

Comparison Item	**Proposed Device, BONTREE PLUS**	**Predicate Device, OSTEON II, K112716**	**Reference Device, TRS PCL Cranial Bone Void Filler, K123633**	**Substantial Equivalence Discussion**
510(k) Number	K251818	K112716	K123633	510(k) Number
Trade/Device Name	BONTREE PLUS	OSTEON II	TRS PCL Cranial Bone Void Filler	Device Name

Comparison Item	Proposed Device, BONTREE PLUS	Predicate Device, OSTEON II, K112716	Reference Device, TRS PCL Cranial Bone Void Filler, K123633	Substantial Equivalence Discussion
Regulation Number	21 CFR 872.3930	21 CFR 872.3930	21 CFR 882.5250	Regulation Number
Regulation Name	Bone grafting material	Bone grafting material	Burr hole cover	Same as the predicate, K112716
Regulatory Class	Class II	Class II	Class II	Same as the predicate, K112716
510(k) Review Panel	Dental	Dental	Neurology	Same as the predicate, K112716
Product Code	LYC	LYC	GXR	Same as the predicate, K112716
Manufacturer	HUDENS BIO Co., Ltd.	GENOSS Co., Ltd.	Tissue Regeneration Systems, Inc.	Manufacturer
Indications for Use	Intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects. ● Periodontal /infrabony defects ● Ridge augmentation ● Extraction Sites (implant preparation /placement) ● Sinus lifts ● Cystic cavities	Intended for use as a bone grafting material to fill, augment or reconstruct periodontal or oral/maxillofacial defects. ● Periodontal/infrabony defects ● Ridge augmentation ● Extraction Sites (implant preparation/placement) ● Sinus lifts ● Cystic cavities	Intended for use in the repair of 13mm neurosurgical cranial burr holes. It should be gently packed into bony voids or gaps of the skeletal system that are not intrinsic to the stability of the bony structure.	Same as the predicate, K112716
Surgical Site	Oral, periodontal	Oral, periodontal	Cranial, skeletal	Same as the predicate, K112716
Components	● Hydroxyapatite (HA) ● Octacalciu	● Hydroxyapatite (HA) ● Beta-	● Hydroxyapat	BONTREE PLUS uses OCP instead of β-TCP, though, both materials are well-established, resorbable calcium phosphates with similar osteoconductive functions and safety profiles. In

Comparison Item	Proposed Device, BONTREE PLUS	Predicate Device, OSTEON II, K112716	Reference Device, TRS PCL Cranial Bone Void Filler, K123633	Substantial Equivalence Discussion
	m phosphate (OCP)	tricalcium phosphate (β-TCP)	ite (HA) • Octacalcium phosphate (OCP) • Polycaprolactone (PCL)	addition, OCP is the same calcium phosphate component used in the cleared reference device (TRS PCL Cranial Bone Void Filler, K123633), further supporting its regulatory precedent and safety profile in bone repair applications. Biocompatibility testing and preclinical performance data of the finished device of BONTREE PLUS confirm that this material difference does neither alter the device's safety or effectiveness profile nor affect substantial equivalence with the predicate, K112716. Accordingly, the material difference does not raise different questions of safety and effectiveness, and BONTREE PLUS remains substantially equivalent to the predicate device under 21 CFR 872.3930.
Material Composition	• HA: 30wt% • OCP: 70wt%	• HA: 25~45wt% • β-TCP: 55~75wt%	N/A	With respect to the Material Composition Ratio Difference, BONTREE PLUS contains 30 wt% HA and 70 wt% OCP, while the predicate contains 25–45 wt% HA and 55–75 wt% β-TCP. This difference does not raise new questions of safety or effectiveness: The HA content (30 wt%) falls within the predicate's HA range, and the resorbable phase is present at comparable proportions. OCP and β-TCP are well-established, resorbable calcium phosphates with similar osteoconductive functions. The biphasic calcium phosphate design and mechanism of action remain unchanged. Both devices consist entirely of calcium phosphate without novel additives. ISO 10993 biocompatibility and preclinical data of BONTREE PLUS confirm no new risks compared to the predicate. Therefore, BONTREE PLUS remains substantially equivalent to OSTEON II (K112716) under 21 CFR 872.3930.
Porosity	40% or more	70%	N/A	Although BONTREE PLUS has a porosity of ≥40% compared to 70% for OSTEON II (K112716), this difference does not raise new questions of safety or effectiveness. BONTREE PLUS maintains an interconnected porous structure adequate for cell migration, fluid exchange, and bone regeneration while preserving mechanical integrity. Preclinical data demonstrate comparable bone ingrowth and remodeling without

Comparison Item	Proposed Device, BONTREE PLUS	Predicate Device, OSTEON II, K112716	Reference Device, TRS PCL Cranial Bone Void Filler, K123633	Substantial Equivalence Discussion
				new risks. Therefore, intended use, technological characteristics, and safety/effectiveness remain unchanged, and substantial equivalence is maintained under 21 CFR 872.3930.
Pore Size	0.1μm or more	250μm	N/A	Although BONTREE PLUS specifies a pore size of ≥0.1 μm and OSTEON II (K112716) reports a macropore size of ~250 μm, this difference does not raise new safety or effectiveness concerns. The 0.1 μm value represents the minimum detectable pore structure, and BONTREE PLUS also contains an interconnected porous architecture that supports osteoconduction and fluid exchange. The predicate's value reflects its dominant macropore size; both devices function as porous calcium phosphate scaffolds for bone ingrowth and resorption. Preclinical data confirm comparable bone regeneration without new risks. Therefore, substantial equivalence is maintained under 21 CFR 872.3930.
Particle Size	0.3~1.4mm	0.2~2.0mm	N/A	BONTREE PLUS has a particle size range of 0.3–1.4 mm, fully within the predicate OSTEON II (K112716) range of 0.2–2.0 mm. Thus, it represents a subset of previously cleared dimensions. This ensures comparable handling, packing, and osteoconductive surface area. Because the particle size falls within an established clinical range for calcium phosphate grafts, it raises no new safety or effectiveness concerns, and substantial equivalence is maintained under 21 CFR 872.3930.
Ca/P Ratio	1.4 ± 0.1	N/A	N/A	Although the predicate does not specify a Ca/P ratio, the 1.4 ± 0.1 ratio of BONTREE PLUS is consistent with the stoichiometric range of octacalcium phosphate and within the established spectrum of resorbable calcium phosphate grafts. Such variations do not alter the osteoconductive mechanism based on scaffold-mediated bone ingrowth and gradual resorption. Biocompatibility and preclinical data confirm no adverse impact on safety or performance. Therefore, this specification does not raise new questions of safety or effectiveness compared to K112716.

Comparison Item	Proposed Device, BONTREE PLUS	Predicate Device, OSTEON II, K112716	Reference Device, TRS PCL Cranial Bone Void Filler, K123633	Substantial Equivalence Discussion
Crystalline Phase Composition	≥ 60%	N/A	N/A	Although the predicate does not specify crystalline phase composition, the ≥60% crystalline phase in BONTREE PLUS is consistent with sintered HA- and OCP-based calcium phosphate grafts. The crystalline structure supports mechanical integrity and controlled resorption without changing the osteoconductive mechanism. While crystallinity may influence resorption rate, it does not introduce new biological risks. Biocompatibility and preclinical data confirm no adverse impact on safety, tissue response, or bone regeneration. Therefore, this characteristic does not raise new questions of safety or effectiveness.
Crystallinity	60% or more	N/A	N/A	Although the predicate does not specify crystalline phase composition, the ≥60% crystalline phase of BONTREE PLUS is consistent with synthetic calcium phosphate graft materials. It provides structural stability and predictable resorption while maintaining the same osteoconductive mechanism as HA-based grafts. Differences in crystallinity do not introduce new constituents or modes of action. Biocompatibility and preclinical studies confirm no adverse impact on safety or performance. Therefore, this specification does not raise new questions of safety or effectiveness compared to K112716.
pH	pH 0.41, pH difference shall be ≤ 1.5.	N/A	N/A	Although the predicate does not specify extraction pH, the ≤1.5 pH difference of BONTREE PLUS falls within the acceptable range for implantable calcium phosphate grafts and reflects normal material–fluid interaction. Such minor variations are not expected to cause tissue irritation due to physiological buffering at the implant site. ISO 10993 biocompatibility testing, including cytotoxicity and irritation assessments, showed no adverse tissue response. Therefore, the pH specification does not introduce new risks or raise new questions of safety or effectiveness.
Supplied Sterile;	Supplied sterile; Gamma radiation	Supplied sterile; Gamma radiation	Supplied sterile; Ethylene	Same as the predicate, K112716

Comparison Item	Proposed Device, BONTREE PLUS	Predicate Device, OSTEON II, K112716	Reference Device, TRS PCL Cranial Bone Void Filler, K123633	Substantial Equivalence Discussion
Sterilization Method			Oxide	
Packaging	Glass vial	Glass vial	N/A	Same as the predicate, K112716
Shelf-life	2 years	N/A	N/A	Labeled shelf life

9. Performance Data

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

A. Biocompatibility Testing

BONTREE PLUS falls under the category of implant device in contact with tissue and/or bone with permanent contact duration (>30 days) (FDA 2023). Based on this categorization, BONTREE PLUS has been evaluated on a risk basis for biocompatibility endpoints according to ISO 10993-1 and FDA's modified biocompatibility matrix Table A.1 as listed in Attachment A of 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"*.

The battery of biocompatibility testing for BONTREE PLUS included the following.

- Cytotoxicity (ISO 10993-5)
- Sensitization (ISO 10993-10)
- Irritation (ISO 10993-23; intracutaneous reactivity / irritation)
- Material-mediated pyrogenicity (ISO 10993-11)
- Acute systemic toxicity (ISO 10993-11)
- Subacute / subchronic systemic toxicity (ISO 10993-11)
- Hemocompatibility (Hemolysis) (ISO 10993-4)
- Genotoxicity – Bacterial Reverse Mutation (Ames) (ISO 10993-3)
- Genotoxicity – Micronucleus Assay (ISO 10993-3)
- Genotoxicity – Chromosomal Aberration Test (ISO 10993-3)
- Implantation- Animal Performance Study, Rabbit Bone Implantation Study 13- and 26-week, (ISO 10993-6:2016)

Chronic toxicity and carcinogenicity were addressed through the chemical characterization, toxicological risk assessment, and biological risk assessment.

B. Animal Study

Pre-clinical study was conducted in a canine dental defect model to evaluate the in vivo bone healing/regeneration ability. The study was comparative between the subject and predicate device. Radiography, histology, and histomorphometry were performed at 4, 8, and 12 weeks post-operation.

a. The Size and Type of Defect: A canine mandibular 1-wall intrabony defect model was used. Box-shaped critical-size defects measuring 4 × 5 mm (length × height) were surgically created in the mandibular alveolar bone.

b. The Types of Histology Stains that Were Done: Histological evaluation was performed using Hematoxylin and Eosin (H&E) staining to assess cellular morphology and inflammatory response, and Masson's Trichrome staining to evaluate and quantify new bone formation within the defect area.

c. Endpoints Assessed (New Bone Formation, Degradation, and Inflammatory Response): Endpoints included new bone formation quantified by micro-CT total bone volume and histomorphometric analysis of new bone area, material degradation and graft integration observed through micro-CT and histology, and inflammatory response evaluated by histological assessment and gingival inflammation scoring.

d. Conclusion (Study Results): The animal study demonstrated that BONTREE PLUS supported significant new bone formation compared with the defect-only control and showed comparable bone regeneration to the predicate, OSTEON II (K112716). Minimal inflammatory response and no material-related adverse reactions were observed, confirming equivalent biocompatibility and bone regeneration performance.

C. Sterilization Tests

The validation of gamma irradiation sterilization was performed following ISO 11137-1 and ISO 11137-2, achieving a sterility assurance level of 10^{-6}.

BONTREE PLUS is provided sterile and is terminally sterilized by gamma irradiation to achieve a Sterility Assurance Level (SAL) of 1×10^{-6}.

- Sterilization validation was conducted in accordance with ISO 11137-1:2006/Amd.2:2018, ISO 11137-2:2013, and ISO 11137-3:2017.
- Bioburden determination and verification sterility testing were conducted in accordance with ISO 11737-1:2018 and ISO 11737-2:2019.

- Bacterial endotoxin testing was performed using the Limulus Amebocyte Lysate (LAL) method in accordance with USP <85> Bacterial Endotoxins Test and met the established limit of <20 EU/device.
- Additionally, rabbit pyrogen testing was conducted under GLP conditions in accordance with ISO 10993-11 and applicable pharmacopeial requirements, demonstrating absence of pyrogenic response.

Shelf-life validation was conducted to demonstrate maintenance of sterility and package integrity over the labeled shelf life. Packaging validation was performed in accordance with ISO 11607-1:2019 and ISO 11607-2:2019.

Seal strength testing was conducted per ASTM F88, dye penetration testing per ASTM F1929, and visual seal integrity testing per ASTM F1886 to verify sterile barrier integrity. These tests confirmed that the packaging system maintains sterility and device integrity throughout the labeled shelf life.

E. Bench Performance Testing

Bench-top performance testing was conducted to characterize the physicochemical and mechanical properties of BONTREE PLUS (synthetic bone graft material), as summarized below:

- Extraction – Buffering Capacity: Conducted in accordance with USP 38 <661> The test confirms buffering interaction with aqueous environments and demonstrates chemical stability consistent with calcium phosphate bone graft materials. These results support substantial equivalence to the predicate, OSTEON II (K112716), which uses similar calcium phosphate chemistry and osteoconductive function.
- Extractable Substances (pH): Performed in accordance with ASTM F619-20 The extraction pH difference (≤1.5) reflects normal interaction between calcium phosphate materials and aqueous solutions. Although not specified for the predicate device, this value is within the acceptable range for implantable calcium phosphate grafts and supports substantial equivalence with the predicate, OSTEON II (K112716),.
- Physical Characterization: Evaluated in accordance with ISO 2591-1 Physical characterization testing confirms that the particle morphology, granule structure, and material consistency of BONTREE PLUS are comparable to those of cleared calcium phosphate bone graft materials. These characteristics are consistent with the technological properties of the predicate OSTEON II (K112716), and support substantial equivalence.
- Scanning Electron Microscopy (SEM) – Dimensional Analysis: Surface morphology and particle dimensions were evaluated using SEM in accordance with the laboratory's validated test method for dimensional measurement SEM analysis confirmed a porous

calcium phosphate microstructure consistent with osteoconductive bone graft materials. The observed morphology supports the same scaffold-based bone regeneration mechanism as the predicate OSTEON II (K112716).

- Elastic Modulus (Compression Testing): Determined using a Universal Testing Machine (UTM) in accordance with ISO 13175-3 Compression testing confirmed that the mechanical integrity of BONTREE PLUS is appropriate for bone graft handling and packing during surgical procedures. The mechanical characteristics are consistent with porous calcium phosphate graft materials and do not introduce different questions of safety or effectiveness relative to the predicate, OSTEON II (K112716),
- Particle Size Distribution (Sieving Method): Conducted in accordance with ISO 2591-1:1988 Testing confirmed that the particle size range of 0.3–1.4 mm falls entirely within the cleared predicate device range of 0.2–2.0 mm (OSTEON II, K112716). Because the particle size represents a subset of previously cleared dimensions, it ensures comparable handling, packing characteristics, and osteoconductive surface area, supporting substantial equivalence with the predicate, OSTEON II (K112716).
- Heavy Metal Study: Tested in accordance with the Korean Pharmacopoeia General Test Methods 66. Heavy Metal Test Methods, (the color of the test solution should not be darker than the control solution). Results demonstrated that heavy metal content remains below pharmacopeial limits and consistent with purified synthetic calcium phosphate materials used in bone grafts. These results confirm chemical purity comparable to other cleared calcium phosphate graft materials and support its substantial equivalence to the predicate OSTEON II (K112716).

All bench testing results demonstrated that the device meets its predetermined acceptance criteria and supports substantial equivalence to the predicate device.

10. Conclusion

The test results indicate that BONTREE PLUS is substantial equivalence to the predicate device OSTEON II.