August 17, 2020

GC America, Inc.
% H. Jenkins
Official Correspondent
Wood Burditt Group
10 E. Scranton Ave., Ste. 201
Lake Bluff, Illinois 60045

Re: K192597
Trade/Device Name: Cytrans Granules
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: August 13, 2020
Received: August 14, 2020

Dear H. Jenkins:

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 Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K192597

Device Name
Cytrans Granules

Indications for Use *(Describe)*
-Augmentation or reconstructive treatment of the alveolar ridge.
-Filling of periodontal defects.
-Filling of defects after root resection, apicocetomy, and cystectomy.
-Filling of extraction sockets to enhance preservation of the alveolar ridge.
-Elevation of the maxillary sinus floor.
-Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
-Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

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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K192597

510(k) Summary

Date prepared: August 17, 2020

Submitter / Contact Person	H. Carl Jenkins The Wood Burditt Group 10 E. Scranton Ave, Suite 201 Lake Bluff, IL 60044 (ph.) 847-234-7500 x 205 (fax) 847-578-0728 (email) hcjenkins@woodburditt.com

Applicant **(Device Distributor)**	GC America Inc. 3737 W. 127th Street Alsip, IL 60803 USA

Device Name

Trade / Proprietary Name	Cytrans Granules
Common Name	Bone Grafting Material, Synthetic
Classification Name	Bone Grafting Material
Classification Panel	Dental
Regulation	21 CFR 872.3930
Product Code	LYC
Classification	2

Reason for 510(k) Submission

The applicant device is a new device.

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Predicate Device Summary Table

Substantial equivalence for the indications for use, safety, efficacy, and technological characteristics is based on Cytrans Granules being substantially equivalent to the following Predicate Device and Reference Device:

- Predicate Device: SynOss Granules (Collagen Matrix) – K072397
- Reference Device: Cerasorb M (Curasan) – K113282

Subject Device	**Predicate Device**	**Reference Device**
Cytrans Granules	SynOss Granules (Collagen Matrix)	Cerasorb M (Curasan)
Subject Device	K072397	K113282

Device Description

Cytrans Granules is composed of carbonate apatite. The material of Cytrans Granules has been formulated in terms of carbonate apatite content to be similar to the mineral content of natural bone. As Cytrans Granules is completely synthetic, there are no animal derived ingredients in the formula.

Cytrans Granules is gradually resorbed and eventually replaced with new bone. Resorption is by osteoclasts under acidic conditions. Cytrans Granules is manufactured by a validated manufacturing process which guarantees batch to batch conformity and reproducibility. It is sterilized via gamma irradiation and will be marketed/sold in sterile vials for single use.

Intended use:

Cytrans Granules is bone graft substitute material for dental use (oral surgery, periodontal surgery, etc.), intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region.

It is used for filling bone defects in the upper and lower jawbones and alveolar bones. It is used to fill a site where the implant is exposed during implant placement, to fill the bone defect during the implant placement procedure.

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Indications for Use:

-Augmentation or reconstructive treatment of the alveolar ridge.
-Filling of periodontal defects.
-Filling of defects after root resection, apicocetomy, and cystectomy.
-Filling of extraction sockets to enhance preservation of the alveolar ridge.
-Elevation of the maxillary sinus floor.
-Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR).
-Filling of peri-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR).

Technological Characteristics

Descriptive Information	**Subject Device Cytrans Granules (GC) K192597**	**Primary Predicate SynOss Granules (Collagen Matrix) K072397**	**Reference Device Cerasorb M (Curasan) K113282**
Intended Use	A synthetic bone grafting material intended to fill, augment, or reconstruct periodontal and or bony defects of the upper or lower jaw.	Synthetic calcium-phosphate-based bone grafting material that is intended for filling of defects and extraction sockets, for augmentation of the alveolar ridge, and for elevation of the maxillary sinus floor.	Resorbable, pure-phase P-TCP matrix with interconnecting porosity for bone regeneration esp. for use in periodontal therapy.
Indications for Use	-Augmentation or reconstructive treatment of the alveolar ridge. -Filling of periodontal defects. -Filling of defects after root resection, apicocetomy, and cystectomy. -Filling of extraction sockets to enhance preservation of the alveolar ridge. -Elevation of the maxillary sinus floor. -Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR). -Filling of periimplant defects in conjunction with products intended for Guided Bone Regeneration (GBR).	-Augmentation or reconstructive treatment of the alveolar ridge. -Filling of periodontal defects. -Filling of defects after root resection, apicocetomy, and cystectomy. -Filling of extraction sockets to enhance preservation of the alveolar ridge. -Elevation of the maxillary sinus floor. -Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR). -Filling of periimplant defects in conjunction with products intended for Guided Bone Regeneration (GBR).	-Augmentation or reconstructive treatment of the alveolar ridge. -Filling of infrabony periodontal defects. -Filling of defects after root resection, apicoectomy, and cystectomy. -Filling of extraction sockets to enhance preservation of the alveolar ridge. -Elevation of the maxillary sinus floor. -Filling of periodontal defects in conjunction with products intended for Guided Tissue Regeneration (GTR) and Guided Bone Regeneration (GBR) -Filling of perio-implant defects in conjunction with products intended for Guided Bone Regeneration (GBR)

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Device Design	Granule Particle size 0.3-0.6 mm (S size), 0.6-1.0 mm (M size)	Granule Particle size 0.35-1.0 mm	Granule Particle size 0.15-0.5 mm, 0.5-1.0 mm, 1.0-2.0 mm
Composition of Materials	Carbonate Apatite, 100% (Carbonate content: ~12%)	Carbonate Apatite, 100% (Carbonate content: ~5%)	β-Tricalcium Phosphate, 100%
Resorption Time	6-24 months Resorption will slow down after covered with newly formed bone.	6-24 months	6-24 months > 99% (150-2000 μm) 65vol%
Phase Purity* (i.e. relative mass percentages crystalline vs. amorphous)	85% (Crystalline)	Crystalline	Crystalline
Ca/P Ratio	1.67/1	1.43/1	1.5/1
Particle Size Range (μg/mm3)	0.3-0.6 mm (S size), 0.6-1.0 mm (M size)	0.250-1.0mm (250-1000μm)	0.150–2.0 mm (150-2000 μm) (150-500/ 500-1000/ 1000-2000μm, provided in cc)
Volumeric Porosity (%)	28%	81	65%
pH	7.8	7.8	7.8
Sintering Temperature	Not Applicable* (*device is fabricated in aqueous solution).	650℃	1000℃
in vitro dissolution @ 25℃ in pH 5.5 after 30 minutes	14.8 mg/L (S size) 10.7 mg/L (M size)	15.9 mg/L	7.3 mg/L
in vitro dissolution @ 25℃ in pH 7.3 after 30 minutes	0.81 mg/L (S size) 0.52 mg/L (M size)	0.52 mg/L	0.42 mg/L
Chemical Composition	Carbonate apatite: 100%	Carbonate apatite: 100%	β-tricalcium phosphate: 100% Ca1O(PO4 C0 3)6(OH) 2

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Carbonate or CO3 Content (%)	12%	5	Not Applicable
Product Code	LYC	LYC	LYC
Crushing strength (N)	2.75 N	0.42 N	1.97 N
Cited Standards	-ISO 14971:2007 -ISO 13779-3:2008 -ISO 13485:2003 -ISO 11137-1:2006 -JIS Z 8841:1993 (TBC) -JIS K 0061:2001 (TBC) -JIS T 0330-3:2012 (ISO 13175-3:2012) -ISO 10993-5:2009 -ISO 10993-6:2007 -ISO 10993-10:2010 -ISO 10993-11:2006 -ISO 10993-12:2007	-ANSI/AAMI/ISO 11137:2003 -ISO 10993, 3rd edition	ASTM F1088 ISO 10993; ASTM F756 ISO 11137, 11737-1 and 2 ISO 14971

Performance Testing:

Nonclinical and clinical testing of Cytrans Granules was conducted to support the performance of the subject device for its intended use. In addition to shelf- life determination and pyrogenicity sampling plan, biocompatibility testing, animal studies and clinical testing were conducted to establish the performance of the subject device.

Biocompatibility testing conducted on the subject device demonstrates that the materials used in the design and manufacture of the subject device are non-toxic and non-sensitizing to biological bone and tissues with intended use. Calcium phosphate bone grafting materials of this composition are known to be biocompatible for this intended use. In order to further confirm the biocompatibility of *Cytans Granules,* the following tests in accordance with ISO 10993 were performed: Cytotoxicity, Sensitization, Genotoxicity (reverse mutation), Genotoxicity (Chromosomal aberration), Intracutaneous Reactivity, Acute Toxicity and Sub-chronic Toxicity. According the specified test conditions, *Cytans Granules* was found to be non-cytotoxic, non-irritating, and non-systemically toxic. Test results were negative with no tissue damage observed.

Animal studies conducted in a beagle dog model, comparing three commercially available bone substitutes at 12 weeks for the reconstruction of alveolar bone defects with simultaneous dental implant installation demonstrated that bone formation occurred faster with Cytrans Granules. Further, when comparing three commercially available bone substitutes in a beagle dog model, new bone formation occurred faster and demonstrated a higher bone-to-implant contact ratio

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after 4 weeks and 12 weeks for the reconstruction of alveolar bone defects of a beagle mandible with simultaneous dental implant installation.

A clinical trial involving three institutions in Japan and a total of 22 cases (ages: 37-77) of patients (not including excluded cases) with indications for sinus floor augmentation during placement of an implant for a maxillary molar (maximum quantity used was 2.5 g) was conducted. The exclusions were: mucosal hypertrophy with suspicion of inflammation, oro-nasal communication from past otolaryngology treatment, use of prohibited concomitant drugs (one case each), and three cases of perforated mucous membrane of the maxillary sinus. Sinus floor augmentation: single-stage treatment group (pre-operative bone thickness: 3.7 mm (minimum) - 6.0 mm (maximum): average 5.2 mm, evaluation period: 6 months (minimum) - 8.5 months (maximum): average 7.5 months. No rotation or movement occurred in any of the cases due to torque loading. Sinus floor augmentation: two-stage treatment group (pre-operative bone thickness: 1.0 mm (minimum) - 5.0 mm (maximum): average 3.4 mm, evaluation period: 6 months (minimum) - 9.5 months (maximum): average 8 months. The implant placement torque was evaluated, with the result of 26.9 N average. Success rate for the treatment was calculated for the combined single-phase and two two-phase treatment groups, and it was confirmed that all major evaluation items exceeded the level deemed to be effective. Furthermore, 7±2 months after the implantation, opacity due to the product or new bone formation was confirmed in the single single-stage group by panoramic X-ray, and the average of 10.5 mm vertical residual bone was confirmed in the two two-stage group by CT imaging. In addition, tissue biopsy confirmed new bone formation in all cases of the two-stage group.

Performance testing demonstrates that (a) the Cytrans Granules product meets specifications in the following categories: chemical composition, particle size, shape, porosity, resorption properties, phase purity, crushing strength, pH, and water solubility; and (b) Cytrans Granules is substantially equivalent to the legally marketed primary predicate, meeting requisite characteristics.

Sterilization:

The device is sterilized to a sterility assurance level (SAL) of 1 x 10^{-6} using a sterilization cycle that has been validated in accordance with FDA's Quality Systems Regulation.

ISO 11137-1:2006	Sterilization of health care products -- Radiation -- Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	14-428

Method Used to Validate the Sterilization Cycle: compliance with ISO 11137-2

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Substantial Equivalence

Cytrans Granules is comparable to other calcium phosphate bone grafting materials on the market such as primary predicate SynOss *(Collagen Matrix) K072397 and reference device* ***Cerasorb M (Curasan) K113282***. The devices feature the similar formulation and indications, with similar particle size distributions, morphology, volumetric porosity, and resorption characteristics. The subject device, Cytrans Granules, and its primary predicate share identical Indications for Use statements, namely to serve as a bone grafting material intended to fill, augment, or reconstruct periodontal or bony defects of the oral and maxillofacial region, as well as peri-implant bony defects. They also share similar material composition and similar resorption profiles.

The primary difference between the subject device and its primary predicate is related to slight mechanical and physical characteristics, such as small differences in pore and particle sizes. The subject device features a slight difference in granule particle size from its primary predicate, ranging from 0.3 – 1.0 mm for Cytrans Granules (GC) K192597 and 0.35 – 1.0 mm for primary predicate SynOss Granules (Collagen Matrix) K072397. To address this difference in the larger granule particle sizes featured in Cytrans Granules, a reference device Cerasorb M (Curasan) K113282 is provided which features a range of pore sizes capturing those of the subject device. However, additional nonclinical testing results demonstrate that the any differences noted between Cytrans Granules and its primary predicate do not raise new concerns. An additional difference noted between the subject device and its primary predicate is volumetric porosity, which is much lower in the subject device when compared to its predicate and reference devices. However, the differences in volumetric porosity do not affect the intended use for demonstrating substantially equivalent bone formation, based on the provided animal and clinical testing.

Conclusion

The applicant device is substantially equivalent in its intended use, technology / principle of operation, ingredients, and performance to the primary predicate device identified in this 510(k) submission. There is no significant difference that raises any new concerns.