Osteogene Tech Corp
℅ James O'connor
Principal and Manager
JMC Medical, LLC
65 Elm Street
Chelmsford, Massachusetts 01824

March 04, 2022

Re: K202675
Trade/Device Name: InRoad® Dental Synthetic Bone Graft
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: February 8, 2022
Received: February 9, 2022

Dear James O'connor:

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 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)*
K202675

Device Name
InRoad® Dental Synthetic Bone Graft

Indications for Use *(Describe)*

InRoad® Dental Synthetic Bone Graft is intended for the filling and reconstruction of multi-walled bone defects such as:

- Defects after removal of bone cysts
- Augmentation of the atrophied alveolar ridge
- Sinus lift and sinus floor elevation (subantral augmenation)
- Filling of alveolar defects following tooth extraction for alveolar ridge preservation
- Filling of extraction defects to create an implant bed
- Filling of two- or multi- walled infra-bony pockets. and bi- and trifurcation defects
- Support function for a membrane in controlled tissue regeneration (CTR)
- Defects after surgical removal of retained teeth or corrective osteotomies
- Other multi-walled bone defects of the alveolar processes

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
OSTEOGENE™ TECH CORP
InRoad® Dental Synthetic Bone Graft
510(k) K202675

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807, this information serves as a Summary of Substantial Equivalence for the use of OSTEOGENE™ TECH InRoad® Dental Synthetic Bone Graft.

I. SUBMITTER

Submitted By: OSTEOGENE™ TECH CORP
75 Oak Street
Norwood, NJ 07648
Phone: 201-367-9321

Contact Person: Dr. Daniel S. Oh, CSO
e-mail: dr.oh@osteogene.com

Date Prepared: March 2, 2022

II. DEVICE

Proprietary Name: InRoad® Dental Synthetic Bone Graft

Common Name: Bone grafting material, synthetic

Classification Name: Bone grafting material

Regulation: 21 CFR 872.3930

Product Code: LYC

III. PREDICATE DEVICE

Predicate Device: Curasan, Osbone® Dental Synthetic Bone Graft, K102872

This predicate device has not been subject to a design-related recall.

Reference Device: GENOSS, OSTEON III Synthetic Bone Graft, K153676

This reference device has not been subject to a design-related recall.

IV. DEVICE DESCRIPTION

InRoad® Dental Synthetic Bone Graft (SBG) is a synthetic, semi-dense porous bioceramic for bone regeneration. It is comprised of 90 ± 5% hydroxyapatite (HA) and 10 ± 5% β-Tricalcium Phosphate (β-TCP). The granules are provided sterile (gamma irradiated) in a capped vial packaged in a sealed tray with lid.

InRoad® Dental SBG granules are designed to resemble trabecular bone structure. The granule structure consists of interconnected primary open pores, a secondary channel-like structure, and tertiary small holes on the surface resulting in a biocompatible, osteoconductive biomaterial. The multi-porous structure of InRoad® Dental SBG makes it possible for the bone cells to migrate into the matrices and for new bone to grow.

InRoad® Dental Synthetic Bone Graft is available in granule form in sizes of 0.3 – 1.0 mm (Small) and 0.8 – 1.8 mm (Large). Reference numbers, descriptions, and volume of granules in the vials are listed below.

REFERENCE #	Description	Volume
HA90D05S	InRoad® Small (0.3~1.0 mm) Dental Synthetic Bone Graft granules	0.5 cc
HA90D10S	InRoad® Small (0.3~1.0 mm) Dental Synthetic Bone Graft granules	1.0 cc
HA90D30S	InRoad® Small (0.3~1.0 mm) Dental Synthetic Bone Graft granules	3.0 cc
HA90D05L	InRoad® Large (0.8~1.8 mm) Dental Synthetic Bone Graft granules	0.5 cc
HA90D10L	InRoad® Large (0.8~1.8 mm) Dental Synthetic Bone Graft granules	1.0 cc
HA90D30L	InRoad® Large (0.8~1.8 mm) Dental Synthetic Bone Graft granules	3.0 cc

V. INDICATIONS FOR USE

InRoad® Dental Synthetic Bone Graft is intended for the filling and reconstruction of multi-walled bone defects such as:

- Defects after removal of bone cysts
- Augmentation of the atrophied alveolar ridge
- Sinus lift and sinus floor elevation (subantral augmentation)
- Filling of alveolar defects following tooth extraction for alveolar ridge preservation
- Filling of extraction defects to create an implant bed
- Filling of two- or multi-walled infra-bony pockets and bi- and trifurcation defects
- Support function for a membrane in controlled tissue regeneration (CTR)
- Defects after surgical removal of retained teeth or corrective osteotomies
- Other multi-walled bone defects of the alveolar processes

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICE

Principle of Use: The InRoad® Dental SBG, the subject device, and Osbone® Dental SBG, the predicate device, are similar in technology and principle of use. For both bone grafts, granule size is selected based on the size of the bony defect to be filled. The bone graft is then applied to the prepared graft bed. The porous structure of the bone graft makes it possible for the bone cells to grow into the matrices. This process is referred to as osteoconductive bone formation.

InRoad® Dental SBG and Curasan Osbone® Dental (K102872) are similar in intended use, area of application (human: oral, periodontal), source (synthetic), form (small and large granules), physical morphology (interconnecting pore structures of varying size), resorption (partially resorbable), packaging (capped vial in a sealed tray and lid in an outer carton), and sterility (gamma irradiation, non-pyrogenic, and intended for one-time single patient use).

Physical form: InRoad® Dental SBG varies slightly from the predicate device Curasan Osbone® Dental in that InRoad® comes in granule sizes between 0.3 mm to 1.8 mm where Osbone has a slightly wider granule size range of 0.25 to 2.0 mm.

The porosity of InRoad® Dental SBG (~ 60 - 80%) is similar to that of Osbone® Dental (~ 80 ±5%). The porosity of the Osteon III, the reference device, is >70%. All three devices have interconnecting pore structure morphology and are synthetic bone grafting material.

Composition: The nominal composition of InRoad® Dental SBG is 90 ± 5% HA and 10 ± 5% β-TCP. InRoad® composition is closest to the predicate Osbone® Dental (100% HA), the difference being that InRoad® Dental SBG has a small amount of β-TCP (<15%). GENOSS Osteon III, the reference device, by comparison has a larger amount of β-TCP than the subject device as it is composed of 40% β-TCP and 60% HA. The subject device, the predicate device, and the reference device have similar HA crystalline composition.

Table. Comparison of InRoad® with Predicate Device and Reference Device

	Subject Device	Predicate Device	Reference Device
Device Name	InRoad® Dental SBG	Osbone® Dental SBG	OSTEON III SBG
Manufacturer	OSTEOGENE™ TECH	Curasan	GENOSS
510(k) Number	K202675	K102872	K153676
Product Code	LYC		
Classification Name	Bone grafting material, synthetic		

	Subject Device	Predicate Device	Reference Device
Indications for Use	Filling and reconstruction of multi-walled bone defects such as: -Defects after removal of bone cysts -Augmentation of the atrophied alveolar ridge -Sinus lift and sinus floor elevation (subantral augmentation) -Filling of alveolar defects following tooth extraction for alveolar ridge preservation -Filling of extraction defects to create an implant bed -Filling of two- or multi-walled infra-bony pockets. and bi- and trifurcation defects -Support function for a membrane in controlled tissue regeneration (CTR) -Defects after surgical removal of retained teeth or corrective osteotomies -Other multi-walled bone defects of the alveolar processes	Filling and reconstruction of multi-walled bone defects, e.g.: -Defects after removal of bone cysts -Augmentation of the atrophied alveolar ridge -Sinus lift and sinus floor elevation (subantral augmentation) -Filling of alveolar defects following tooth extraction for alveolar ridge preservation -Filling of extraction defects to create an implant bed -Filling of two- or multi-walled infra-bony pockets. and bi- and trifurcation defects -Support function for a membrane in controlled tissue regeneration (CTR) -Defects after surgical removal of retained teeth or corrective osteotomies -Other multi-walled bone defects of the alveolar processes	-Periodontal/ Infrabony defects - Ridge augmentation -Extraction sites (implant preparation / placement) - Sinus lifts
Application	Human: Oral, Periodontal		
Performance function	Osteoconductive bone formation		
Source	Synthetic		
Composition	90 ± 5% HA	100% HA	60% HA

	Subject Device	Predicate Device	Reference Device
	10 ± 5% β-TCP		40% β-TCP
Form	Granules, Small and Large	Granules, Small and Large	Granules, Small, Medium, and Large
Particle size	0.3~1.0 mm 0.8~1.8 mm	0.25-1.0 mm 1.0-2.0 mm	0.2~0.5 mm 0.5~1.0 mm 1.0~2.0 mm
Porosity (Nominal)	~60 – 80%	~ 80 ± 5%[1]	~80%[2]
Physical morphology	Interconnecting pore structures		
Crystallinity (%)	Small granules: 71 – 91 Large granules: 98 – 99[3]	71 – 97[3] ≥ 95[4]	>70[2]
Resorption	Partially resorbable	Partially resorbable	Partially resorbable[5]
Packaging	Vial in sealed tray with outer carton	Vial in sealed tray with outer carton	Vial in sealed tray, syringe in sealed tray with outer cartons
Sterility	Sterile (Gamma Irradiation); Non-pyrogenic; One-time single patient use		

[1]Nominal from K102872, [2]Nominal from K153676, [3]From testing, [4]From IFU, [5]Based on composition

VII. PERFORMANCE DATA

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

Biocompatibility Testing: InRoad® Dental SBG falls under the category of implant device in contact with tissue and/or bone with permanent contact duration (>30 days) (FDA 2016). Based on this categorization, InRoad® Dental Synthetic Bone Graft 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 InRoad® Dental SBG included the following.

- Cytotoxicity
- Sensitization

- Irritation
- Acute systemic toxicity
- Material mediated pyrogenicity
- Subacute / subchronic toxicity
- Genotoxicity – mouse lymphoma assay
- Genotoxicity – bacterial reverse mutation study
- Implantation
- Chronic toxicity
- Carcinogenicity

InRoad® Dental SBG has been found to be biocompatible for all biological effects evaluated as an implant that stays in the body for more than 30 days.

Animal Testing: Animal testing was conducted to evaluate the substantial equivalence of small and large InRoad® Dental Synthetic Bone Graft in a one-wall periodontal defect model in dogs in conjunction with a US marketed membrane. Results were compared to defects treated with the US marketed predicate device with the same US marketed membrane, and untreated [sham] defects at intervals of 4, 8, and 12 weeks.

The results were analyzed through animal health observation, radiographic assessment, micro-CT evaluation with statistical analysis, histopathological evaluation and histomorphometry.

These studies procedures, implantations, observations, analyses, and assessments allowed for the successful evaluation of substantial equivalence for two test article bone grafting materials while conforming to ISO 10993-6 *Biological evaluation of medical devices -- Part 6: Tests for local effects after implantation*.

The results indicate that the two test article bone grafts, small granule InRoad® Dental SBG and large granule InRoad® Dental SBG were biocompatible, and demonstrated equivalent performance for endpoints assessed including morphometric analysis of new bone growth and residual synthetic bone graft in a one-wall periodontal defect model in dogs when compared to sites treated with the US marketed predicate device, Osbone® Dental synthetic bone graft material.

Sterilization and Shelf-life Testing: The VDmax^{25} gamma sterilization validation method, ISO 11137-2 was used to show InRoad® Dental SBG as packaged results in a sterility assurance level (SAL) 1x10^{-6} for all devices. Packaging integrity testing per ASTM F1140 and ASTM D3078 showed that shipping, sterilization, and aging would not compromise the ability of the packaging to maintain sufficient strength and seal characteristics when products are sealed in trays to specification and packaged in shelf cartons and shipping cartons.

Product performance verification was conducted again after sterilization, transportation simulation, and accelerated aging to equivalent to 1-year real time aging confirm that InRoad®

Dental SBG characterization was not significantly changed by these processes. The evaluation showed that the material composition and granule size were not affected by sterilization, transportation simulation, and aging.

The successful transit testing and package integrity testing with accelerated aging equivalent to 1-year real time aging showed that the packaging can last for at least 1 year and can therefore be labeled with a 1-year shelf-life.

InRoad® Dental SBG does not incorporate electrical components or software.

No clinical testing was performed with InRoad® Dental SBG.

VIII. CONCLUSIONS

InRoad® Dental SBG, the subject device, and Osbone® Dental SBG, the predicate, have been shown to be equivalent in technology, function, and use. They are equivalent in form, structure, and composition. InRoad® Dental SBG and Osbone® Dental SBG performed similarly in an animal study at 12 weeks.

InRoad® Dental SBG has been shown to be biocompatible and through an animal study has been shown to have equivalent performance as the predicate device at 12 weeks. Its packaging has been shown to have sufficient integrity after sterilization, transportation simulation, and accelerated aging to be labeled with a maximum 1-year shelf-life.