Dimension Inx Corp.
Ramille Shah
Chief Science Officer
3440 S Dearborn St. Suite 142S
Chicago, Illinois 60616

December 30, 2022

Re: K213260
Trade/Device Name: CMFlex™
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: December 19, 2022
Received: December 19, 2022

Dear Ramille Shah:

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,

Andrew I. Steen -S

Andrew I. 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)*
K21360

Device Name
CMFlex(TM)

Indications for Use *(Describe)*

CMFlex™ is indicated for filling and/or augmenting maxillofacial, mandibular, and intraoral osseous defects. Indications include:

- Intrabony periodontal osseous defects
- Furcation defects
- Bony defects or bony deficiencies of the alveolar ridge
- Intraoral, maxillofacial, and mandibular augmentation
- Bony defects of the upper or lower jaw
- Filling of tooth extraction sites
- Sinus elevation grafting

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

DEVICE TRADE NAME
CMFlex™

MANUFACTURER
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DATE PREPARED
December 30, 2022

CLASSIFICATION
Bone Grafting Material, Synthetic (21 CFR 872.3930)

PRODUCT CODE
LYC

PRIMARY PREDICATE
Trade name: OsteoScaf™
Common name: Bone Grafting Material, Synthetic
510(k) number: K101827

REFERENCE DEVICE
Trade name: Easy-Graft®
Common name: Bone Grafting Material, Synthetic
510(k) number: K131385

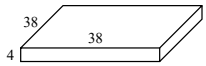
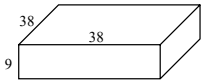
INDICATIONS FOR USE
CMFlex™ is indicated for filling and/or augmenting maxillofacial, mandibular, and intraoral osseous defects. Indications include:
- Intrabony periodontal osseous defects
- Furcation defects
- Bony defects or bony deficiencies of the alveolar ridge
- Intraoral, maxillofacial, and mandibular augmentation
- Bony defects of the upper or lower jaw
- Filling of tooth extraction sites
- Sinus elevation grafting

DEVICE DESCRIPTION

CMFlex™ is a synthetic bone grafting material provided in block form of varying sizes (See Table 1.1) that can be easily trimmed or cut by the surgeon to fit the patient's bone defect(s). CMFlex™ is composed of majority synthetic hydroxyapatite powder bound by minority biodegradable polylactide-co-glycolide. CMFlex™ is fabricated via extrusion-based 3D-printing of liquid inks into regular porous structures. The combined macroscopic 3D-printed porosity, microporosity within the printed struts, and micron-sized hydroxyapatite particles gives CMFlex unique microstructural and physical properties. CMFlex™ is an osteoconductive, highly absorbent, and flexible bone graft that can be used in defects where new bone is needed. Although it is not intended for immediate load bearing applications, the implant remodels over time and is replaced by new bone tissue, functioning in the same manner as the predicate device. The blocks are provided sterile and are intended for single use. There are no accessories associated with CMFlex™.

CMFLEX™ BLOCK SIZES AND VOLUMES

Table 1.1. CMFlex™ Block Sizes and Volumes

Product	Dimensions (mm)	Approximate Volume
CMFlex™ Block, 1cc		1 cc
CMFlex™ Block, 6cc		6 cc
CMFlex™ Block, 13cc		13 cc

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS

Table 1.2. CMFlex™ as Compared to Predicate and Reference Devices

	Subject Device	Primary Predicate Device	Secondary Predicate Device	Comparison
Trade Name	CMFlex™	OsteoScaf™	Easy-Graft®	N/A
Manufacturer	Dimension Inx Corp.	Texas Innovative Medical Devices (DBA) Skeletal	Guidor®	N/A
510(k) Number	K213260	K101827	K131385	N/A
Product Code	LYC			Same product code
Device Class	Class II			Same device class
Device Classification	Bone grafting material, synthetic			Same device classification

Indications for Use	Indicated for filling and/or augmenting maxillofacial, mandibular, and intraoral osseous defects. Indications may include: - Intrabony periodontal osseous defects - Furcation defects - Bony defects or bony deficiencies of the alveolar ridge - Intraoral, maxillofacial, and mandibular augmentation - Bony defects of the upper or lower jaw - Filling of tooth extraction sites - Sinus elevation grafting	Indicated for filling and/or augmenting intraoral/maxillofacial osseous defects, such as intrabony periodontal osseous defects, furcation defects, augmentation of bony defects of the alveolar ridge, filling of tooth extraction sites, and sinus elevation grafting.	Indicated for the treatment of intraoral / maxillofacial osseous defects. Dental and maxillo-facial indications may include: extraction defects (alveolar ridge preservation), periodontal defects, pen-implant defects, augmentation of deficient alveolar crest, sinus floor augmentation, defects after surgical extractions, defects after removal of bony cysts, defects after root resection or apicoectomy, defects after removal of autologous bone.	Intended use includes elements of the predicate devices, supported by performance testing in canines

Prescription/OTC	Prescription			All require prescription
Composition	90% HA 10% PLG	78% CP 22% PLG	99% β-TCP 1% PLG N-methyl-2-pyrrolidone	All devices comprised of a majority calcium phosphate component combined with a degradable polymer component
Physical Morphology	Interconnecting pore structure			Similar pore morphology
Porosity (Nominal)	85%	80%	53%	Similar porosity to primary predicate
Pore Size	0.20 – 0.27 mm	0.20 mm	0.23 mm	All devices have similar pore sizes
Form	Block	Particulate, Cylinder, Block	Granule	Similar form factor to primary predicate
Crystallinity	96%	Not Available	92%	Similar crystallinity to secondary predicate
Resorption[1]	Resorbable	Resorbable	Resorbable	Similar resorption characteristics to primary predicate
Sterility	Sterile; One-time single patient use	Sterile; One-time single patient use	Sterile; One-time single patient use	All devices are sterile and for single use only

[1]Based on composition

Device Intended Use and Descriptions

CMFlex™, OsteoScaf™, and Easy-Graft® are all sterile, porous, ceramic-polymer composite single-use bone grafting materials intended for use in the filling, augmenting, or treating intraoral/maxillofacial defects. All three are class II devices and fall under the same product code, LYC.

Device Compositions and Resorption

CMFlex™, OsteoScaf™ and Easy-Graft® are comprised of discrete micro-scale, spherical calcium phosphate ceramic particles (90, 78, 99 wt.%, respectively) and the biodegradable polyester binder, poly(lactide-co-glycolide), or PLG, (10, 22, 1 wt.%, respectively). The phase of the calcium phosphate component of CMFlex™ is primarily synthetic hydroxyapatite, with minor amounts of beta tricalcium phosphate (B-TCP), while the phases of the calcium phosphate components of OsteoScaf™ and Easy-Graft® are minority hydroxyapatite, with majority di/tetra calcium phosphate and β-TCP, respectively. The calcium phosphate components of CMFlex™ and Easy-Graft® are primarily crystalline (>90%) and the particles comprising CMFlex™ are 23 μm in diameter on average, while those of OsteoScaf™ are 27.5 μm on average. The difference in composition among the devices primarily affect the rate of resorption of the devices, but do not affect the substantial equivalanceof the devices for their intended use.

Device Porosity
Like CMFlex™, OsteoScaf™, and Easy-Graft® possess interconnected micro-and macro-pores formed by overlapping fibers or bound calcium phosphate particles. While CMFlex™ and OsteoScaf™ have total porosity exceeding 80 vol.%, Easy-Graft® had a measured porosity of 53.4 vol.%; however, this value does not include the interconnected porosity within the larger calcium phosphate particles that comprise the majority of Easy-Graft® (which could not be accurately measured). Thus, the actual total porosity of Easy-Graft® may be significantly greater than 53.4 vol.%. and more similar to CMFlex™ and OsteoScaf™ (both >80% porosity with 0.25-1.20 mm pore size). Like CMFlex™, OsteoScaf™ and Easy-Graft® are flexible or moldable, absorb fluid, and are bioresorbable.

Device Form Factors and Volumes
CMFlex™ and OsteoScaf™ are comparable in form factors and sizing: CMFlex™ is available in blocks of varying volumes, while OsteoScaf™ is available in blocks, cylinders, and particulates. Like the various OsteoScaf™ form factors, the various CMFlex™ block volume options are provided as a convenience to the surgeon. Both CMFlex™ and OsteoScaf™ may be further trimmed to ensure an appropriate, custom fit to the patient's defect. Easy-Graft® is available in multiple volumes, but rather than solid form factors, it comes as a kit of PLG coated calcium phosphate particles that are mixed with solvent prior to injection into boney defect. All CMFlex™ volumes share a single "indications for use" statement, which is common to the "indications for use" statement provided for the OsteoScaf™ and Easy-Graft® predicate devices.

PERFORMANCE DATA
The following non-clinical and preclinical tests were performed to support a demonstration of substantial equivalence:

Table 1.3 Substantial Equivalence Performance Testing Summary

Purpose	Method	Conclusions (based on testing results and published information)
Chemical composition	Thermogravimetric analysis	The subject and predicate devices are composed of a majority calcium phosphate component and minority biodegradable polyester component.
Crystallinity (of calcium phosphate component)	X-ray diffraction, ASTM F2024-10R21	The subject and predicate devices have calcium phosphate crystallinities >90%.
Calcium phosphate particle morphology	Scanning electron microscopy	The subject and predicate devices possess spherical calcium phosphate particles.
Pore structure	Scanning electron microscopy	The subject and predicate devices have interconnected pores around 0.2mm and primary pores around 1mm.
Porosity	Porosimetry (BET analysis)	The subject and predicate devices have porosities greater than 50%.
Mechanical strength (compressive)	Compressive mechanical testing, ASTM D695-15	The devices provide adequate handling properties and strength to ensure dimensional integrity when handled by the surgeon and delivered to bony application sites; devices have similar compressive properties.
pH in phosphate buffered saline	ASTM F1635-16	The subject and predicate device have similar pH.
Biocompatibility	ISO 10993 series of standards	Devices passed cytotoxicity, sensitization, irritation, material-mediated pyrogenicity, genotoxicity, and systemic toxicity testing according to ISO 10993.

Performance in animal model	Canine critical sized defect model and ISO 10993-6	CMFlex™ was evaluated for performance and biocompatibility as compared to the predicate device in a one-wall dental defect canine model at 4, 8, and 12 weeks. Assessments included radiography, microCT, and histomorphometric analysis. Endpoints included new bone growth, residual implant material, preservation of ridge (height, width, depth), changes to surrounding bone, and any significant adverse findings (i.e., exuberant necrosis, proliferative granulation tissue/fibrosis, extensive inflammation, or evidence of infection). Results demonstrated that CMFlex™ was able to maintain ridge height, width, and depth and showed similar bone forming capacity and steady state inflammatory response accompanying the absorption process when compared to the predicate device.
Sterilization Validation	Pre-Sterilization Bioburden (ISO 11737-1); LAL Endotoxin (USP<85>); Chamber Mapping; Residuals testing; Bioburden Recovery, Inactivation Kinetics (ISO 11138-1); Performance Qualification (ISO 11138-1:2017, ISO 11138-7:2019, ISO 14937:2009)	CMFlex™ passed all acceptance criteria for validating the end sterilization method.
Shelf Life	Device properties after accelerated and real time aging: Compressive mechanical testing, polymer molecular weight, ceramic composition and crystallinity (ASTM F2024:2021), and microstructure (SEM)	CMFlex™ had no significant mechanical property changes or clinically meaningful compositional (ceramic and polymer component) and microstructural changes after accelerated (12-month simulation) and real-time aging (6 months and 12 months).
Package Integrity Testing (Initial and aged samples)	ASTM F2096; ASTM F88	CMFlex™ packaging passed all package integrity testing as is and after accelerated (12-month simulation) and real-time aging (6 months and 12 months).

CONCLUSIONS

CMFlex™ was compared with the identified predicate devices based on the indications for use, composition, porosity, mechanical strength, biocompatibility testing, and performance studies. CMFlex™ has similar compositional components (e.g., a combination of a biodegradable polymer and calcium phosphate particles), microstructural properties (percent porosity and pore size), pH, and compressive mechanical characteristics. Furthermore, CMFlex™ passed all biocompatibility testing per ISO 10993, and head-to-head comparison with the predicate in a canine critically sized dental defect model showed similar bone forming capacity associated with device remodeling and osteoconduction over time. Based on these studies, the subject device, CMFlex™ is found to be substantially equivalent to the predicate device.