April 14, 2022

Zest Anchors, LLC
Richard Hines
Regulatory Affairs Manager
2875 Loker East
Carlsbad, California 92026

Re: K220252
Trade/Device Name: High Retention Attachment System
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 24, 2022
Received: March 28, 2022

Dear Richard Hines:

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
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)*

K220252

Device Name

High Retention Attachment System

Indications for Use *(Describe)*

The High Retention Attachment System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system. The High Retention Attachment System is compatible with the following implants:

Implant Manufacturer	Implant System	Implant Diameter
Ace Surgical	Infinity OCTAGON	3.3, 4.1, 4.8
	Infinity TRI-CAM	3.5, 4.3, 5.0
	Infinity Internal Hex	3.7, 4.1, 4.7, 5.1
BioHorizons	Tapered Internal	3.0
	Tapered Plus	3.8
	Laser-Lok	3.0
Biomet 3i	3iT3, NanoTite, OSSEOTITE	3.25, 3.75, 4.0
Blue Sky Bio	Quattro	3.3, 4.1, 4.8
	One Stage	3.3, 4.1, 4.8
Camlog	SCREW-LINE ROOT-LINE 2	3.3, 3.8, 4.3, 5.0
	SCREW-LINE	3.3, 3.8, 4.3, 5.0
Dentsply	Astra Tech OsseoSpeed EV	3.6, 4.2, 4.8
	Xive Frialit-2	3.4, 3.8, 4.5, 5.5
	Ankylos C/X	3.5
	Astra Tech OsseoSpeed TX	3.5, 4.0, 4.5, 5.0
Hiossen, Inc.	SS	3.5, 4.0, 4.5
	ET, TS	3.5, 4.0, 4.5, 5.0, 6.0, 7.0
	US	3.5, 3.3, 4.5, 4.0, 5.0, 6.0, 7.0
Implant Direct	Swish Plus	4.1, 4.8
	SwishTapered	4.1, 4.8
	InterActive	3.2, 3.7, 4.3, 5.0
	ReActive	3.7, 4.2, 4.7, 5.7
	RePlant	3.5, 4.3, 5.0
	Legacy 1, 2, 3, 4	3.7, 4.2
	Legacy 2, 3, 4	3.2, 4.7, 5.2
	Legacy 1, 3	5.7
	Legacy 2, 4	5.7, 7.0
	Legacy 1	4.7
IDS	MegaGen Any Ridge	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0
Keystone	PrimaConnex	3.5, 4.1, 5.0
	Genesis	3.5
	TILOBEMAXX	7.0, 8.0, 9.0
MIS	C1	3.3, 3.75, 4.2
	V3	3.3, 3.9, 4.3, 5.0
	SEVEN	3.3
	M4	3.3
Nobel	Replace, Replace Select, NobelSpeedy	3.5, 4.3, 5.0
	NobelActive, NobelParallel CC, NobelReplace CC	3.5, 4.3, 5.5
	Branemark, Nobel Speedy, Groovy	3.3, 3.75, 4.0, 5.0
OCO Biomedical	Engage	3.25, 4.0, 5.0
Southern Implants	Tri-Nex	3.5, 4.3, 5.0
	Tri-MAX7	7.0
Straumann	Roxolid SLActive, Roxolid SLA	3.3, 4.1, 4.8
Zest Dental Solutions	Locator Overdenture Implant System	2.4, 2.9, 3.5, 3.9, 4.4, 4.9
Zimmer Dental	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	3.7, 4.1, 4.7, 6.0
	Spline Reliance Cylinder	3.25, 4.0, 5.0
	Spline Twist	3.75

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 – K220252

High Retention Attachment System

i. General Information on Submitter

Applicant: Zest Anchors, LLC
Address: 2875 Loker Avenue, East
Carlsbad, CA 92010 USA
Telephone: 442-244-4835, ext. 480
Cellphone: 949-395-8795
Contact Person: Richard Hines
Contact Title: Regulatory Affairs Manager
Email: richard.hines@zestdent.com
Date Prepared: April 13, 2022
Establishment Registration: 3006796211

ii. General Information on Device

Proprietary Name: **High Retention Attachment System**
Common Name: Dental Implant Abutment
Classification Name: Endosseous dental implant abutment (21 CFR 872.3630)
Regulatory Class: II
Product Code: NHA (Abutment, Implant, Dental, Endosseous)

iii. Predicate Device

Predicate Device	**510(k) Number**
High Retention Attachment System: Zest Anchors, LLC	K213391
Reference Devices	**510(k) Number**
Locator Overdenture Implant System, Zest Anchors, LLC	K120198
Locator Overdenture Implant System, Zest Anchors, LLC	K203701

iv. Description of Device

The High Retention Attachment System is a system that provides rigid connection of fixed, partial, and full arch restorations (fixed/detachable hybrid dentures) to endosseous dental implants. It consists of abutments, attachment housings, inserts and seating and removal tools. The abutments are provided in various cuff heights with the implant and abutment connection specific to the Zest Anchors, LLC or OEM implant. The subject device abutments are made of titanium alloy conforming to ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401) and are TiN (titanium nitride) coated.

The High Retention Attachment System is as provided with an abutment (LOCATOR Attachment) and the surgical instrumentation necessary to place the implant.

The High Retention Attachment System is designed to accommodate a path of insertion divergence of up to 20° per implant and no more than 40° of divergence between implants.

The abutments are identical to the High Retention Attachment System devices cleared in the predicate, K213391, with the main difference being an additional implant system compatibility. The additional compatible implant system, Zest Anchors, LLC's Locator Overdenture Implant (LODI) implants, were previously cleared in K120198 and K203701 and are included as reference devices, in the K220252 submission.

v. Indication for Use

The High Retention System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system. The **High Retention Attachment System is compatible with the following implants:**

Implant Manufacturer	Implant System	Implant Diameter
Ace Surgical	Infinity OCTAGON	3.3, 4.1, 4.8
	Infinity TRI-CAM	3.5, 4.3, 5.0
	Infinity Internal Hex	3.7, 4.1, 4.7, 5.1
BioHorizons	Tapered Internal	3.0
	Tapered Plus	3.8
	Laser-Lok	3.0
Biomet 3i	3iT3, NanoTite, OSSEOTITE	3.25, 3.75, 4.0
Blue Sky Bio	Quattro	3.3, 4.1, 4.8
	One Stage	3.3, 4.1, 4.8
Camlog	SCREW-LINE ROOT-LINE 2	3.3, 3.8, 4.3, 5.0
	SCREW-LINE	3.3, 3.8, 4.3, 5.0
Dentsply	Astra Tech OsseoSpeed EV	3.6, 4.2, 4.8
	Xive Frialit-2	3.4, 3.8, 4.5, 5.5
	Ankylos C/X	3.5
	Astra Tech OsseoSpeed TX	3.5, 4.0, 4.5, 5.0
Hiossen, Inc.	SS	3.5, 4.0, 4.5
	ET, TS	3.5, 4.0, 4.5, 5.0, 6.0, 7.0
	US	3.5, 3.3, 4.5, 4.0, 5.0, 6.0, 7.0
Implant Direct	Swish Plus	4.1, 4.8
	SwishTapered	4.1, 4.8
	InterActive	3.2, 3.7, 4.3, 5.0
	ReActive	3.7, 4.2, 4.7, 5.7
	RePlant	3.5, 4.3, 5.0
	Legacy 1, 2, 3, 4	3.7, 4.2
	Legacy 2, 3, 4	3.2, 4.7, 5.2
	Legacy 1, 3	5.7
	Legacy 2, 4	5.7, 7.0
	Legacy 1	4.7
IDS	MegaGen Any Ridge	3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5, 8.0
Keystone	PrimaConnex	3.5, 4.1, 5.0
	Genesis	3.5
	TILOBEMAXX	7.0, 8.0, 9.0
MIS	C1	3.3, 3.75, 4.2
	V3	3.3, 3.9, 4.3, 5.0
	SEVEN	3.3
	M4	3.3
Nobel	Replace, Replace Select, NobelSpeedy	3.5, 4.3, 5.0
	NobelActive, NobelParallel CC, NobelReplace CC	3.5, 4.3, 5.5
	Branemark, Nobel Speedy, Groovy	3.3, 3.75, 4.0, 5.0
OCO Biomedical	Engage	3.25, 4.0, 5.0
Southern Implants	Tri-Nex	3.5, 4.3, 5.0
	Tri-MAX7	7.0
Straumann	Roxolid SLActive, Roxolid SLA	3.3, 4.1, 4.8
Zest Dental Solutions	Locator Overdenture Implant System	2.4, 2.9, 3.5, 3.9, 4.4, 4.9
Zimmer Dental	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	3.7, 4.1, 4.7, 6.0
	Spline Reliance Cylinder	3.25, 4.0, 5.0
	Spline Twist	3.75

vi. Predicate Device Comparison

The following table compares the Indications for Use and key technological characteristics of the subject and predicate device:

Characteristic / Feature	***High Retention Attachment System*** **(Subject Device)**	**High Retention *Attachment* System (*Predicate Device* – K213391)**	**Locator Overdenture Implant System (*Reference Device #1* – K120198)**	**The Locator Overdenture Implant System (*Reference Device #2* – K203701)**	**Comparison**
Reason for predicate or reference	**n/a**	**Indications, function, material of insert, mechanical (retention) performance**	**Design of implant added to compatibility table**		Predicate is unchanged and reference device is added to cleared compatibility table
Indication for use	Locator High Retention Attachment System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system.	High Retention Attachment System is designed to support fixed, partial or full arch restorations on endosseous dental implants in the mandible or maxilla for the purpose of restoring masticatory function. It is used in fixed hybrid restorations that can be attached with a snap-in system.	Locator Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla.	The Locator Overdenture Implant System is designed to retain overdentures or partial dentures in the mandible or maxilla. Immediate loading is indicated when good primary stability has been achieved and with appropriate occlusal loading.	**Similar:** The subject and the primary predicate K223391 have identical indications for use, with the exception of an additional implant system compatibility for the subject devices. The additional compatible implant system, Zest Anchors, LLC's Locator Overdenture Implant (LODI) implants, were previously cleared in K120198 and K203701, and are included as reference devices.
FDA Product Code	NHA (Abutment, Implant, Dental, Endosseous) 21 CFR 872.3630	NHA (Abutment, Implant, Dental, Endosseous) 21 CFR 872.3630	DZE (Implant, Endossesous, Root-Form) 21 CFR 872.3640	DZE (Implant, Endossesous, Root-Form) 21 CFR 872.3640	**Substantially Equivalent:** The subject device have demonstrated substantial equivalence to the primary predicate device, K213391, in that they utilize identical materials, fundamental designs, intended use and principles of operation. The reference devices, K120198 and K203701, are only included as reference devices for additional implant system compatibilities.
DESIGN					
Abutment platform diameter	2.3 mm to 7.0 mm, multiple systems	2.3 mm to 7.0 mm, multiple systems	N/A	N/A	**Substantially Equivalent.** Predicate and subject abutment platform diameters are identical.
Abutment angle	**Straight**	**Straight**	N/A	N/A	**Substantially Equivalent.** Predicate and subject abutment angles are identical
Abutment / implant interface	Conical, External Hex, Internal Hex, Internal Multi Lobe	Conical, External Hex, Internal Hex, Internal Multi Lobe	External Hex	External Hex	**Substantially Equivalent.** Predicate and subject device abutment/implant interfaces are identical.

Divergence Allowance	20°/40° (except when not allowed by the implant manufacturer)	20°/40° (except when not allowed by the implant manufacturer)	N/A	N/A	**Substantially Equivalent.** Divergence allowance is unchanged from the predicate device.
Prosthesis attachment type	PEEK insert retained in denture attachment housing	PEEK insert retained in denture attachment housing	N/A	N/A	**Substantially Equivalent.** Predicate and subject device prosthesis attachment type are identical.
Materials					
Abutment or Implant Material	**Abutment:** Ti-6Al-4V ELI	**Abutment:** Ti-6Al-4V ELI	**Implant:** Ti 6Al-4V ELI	**Implant:** Ti 6Al-4V ELI	**Substantially Equivalent.** both the abutment and the implants in the subject, predicate, and reference devices are made from the same titanium alloy (Ti-6Al-4V ELI).
Device Material Surface Treatment	**Abutment:** TiN	**Abutment:** TiN	**Implant:** Resorbable Blast Media (RBM) using MCD Apatatic Abrasive	**Implant:** Resorbable Blast Media (RBM) using MCD Apatatic Abrasive	**Substantially Equivalent.** Predicate and subject device use identical surface treatment process.
Prosthetic retention component	PEEK	PEEK	N/A	N/A	**Substantially Equivalent.** Predicate and subject device retention components are identical.
Reference Implant Size	N/A	N/A	2.4mm, 2.9mm	3.5mm, 3.9mm, 4.4mm, 4.9mm	Reference Devices are cleared for implants of 2.4mm to 4.9mm in diameter
Sterilization					
Sterile	No	No	Yes	Yes	**Substantially Equivalent.** Predicate and subject device are both supplied non-sterile.

As noted in the table above, the subject and predicate devices are identical. Fatigue testing according to ISO 14801: 2016 was performed for Zest Anchors, LLC's Locator Overdenture Implant (LODI) implants (K120198/K203701) and leveraged to support modifications to the K213391 compatibility table.

vii. Summary of Non-Clinical Performance Testing

No new testing was performed as a part of this submission for the determination of substantial equivalence.

Fatigue testing, sterilization, and biocompatibility testing are all leveraged from previous submissions

MR safety for the subject device system was based on the “worst-case” of the entire system including all variations (all compatible implant bodies, dental abutments, and fixation screws) and material composition. The “worst-case” assessment includes an evaluation of the High Retention Attachment System devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan. "Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795).

In addition, the “worst-case” MR Safety rationale addressed parameters per the FDA guidance, “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment,” including magnetically induced displacement force and torque.

viii. Substantial Equivalence

The risk management activities and results of the other activities described above provide reasonable assurance that the subject devices have demonstrated substantial equivalence to the predicate devices in the that they utilize the same materials and fundamental designs and also have the same intended use and principles of operation.