April 9, 2026

Zest Anchors, LLC
Maleata Hall
Director of Regulatory Affairs
2875 Loker Ave. E
Carlsbad, California 92010

Re: K260555
Trade/Device Name: LOCATOR® Angled Abutment
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: March 12, 2026
Received: March 13, 2026

Dear Maleata Hall:

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 13485 clause 8.3 (Nonconforming product), ISO 13485 clause 8.5.2 (Corrective action), and ISO 13485 clause 8.5.3 (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 ISO 13485 clause 7.5) and document changes and approvals in the Medical Device File (ISO 13485 clause 4.2.3).

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,

ANDREW I. STEEN -S
2026.04.09 12:16:19 -04'00'

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K260555

Device Name

LOCATOR® Angled Abutment

Indications for Use *(Describe)*

The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient.

IMPLANT COMPATIBILITY

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
LAA 15°, Straumann, BLX	Straumann	3.5, 3.75, 4.0, 4.5	BLX	Regular Base	2.9	Bone Level
		5.0, 5.5, 6.5	BLX	Wide Base	2.9	Bone Level
LAA 15°, Nobel (NP)	Nobel	3.5	NobelActive, NobelParallel CC, NobelReplace CC	Narrow Platform	3.0	Conical
	Implant Direct	3.2, 3.7	InterActive	N/A	3.0	Conical
		3.2, 3.7, 4.2, 4.7	Simply Iconic	N/A	3.0	Conical
LAA 15°, Nobel (RP)	Nobel	4.3	NobelActive, NobelParallel CC, NobelReplace CC	Regular Platform	3.5	Conical
	Implant Direct	4.3, 5.0	InterActive	N/A	3.4	Conical
		4.7, 5.2, 5.7	Simply Iconic	N/A	3.4	Conical
LAA 15°, Neodent (GM)	Neodent	3.5, 3.75, 4.0, 5.0, 6.0	Helix GM	N/A	3.0	Conical / Grand Morse
		3.5, 4.3, 5.0	Drive GM	N/A		Conical / Grand Morse
		3.5, 3.75, 4.0, 5.0	Titamax GM	N/A		Conical / Grand Morse
LAA 15°, TSV	ZimVie	3.7 & 4.1 Green	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	3.5	Internal Hex
		4.7 Purple	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	4.5	Internal Hex
	Implant Direct	3.7, 4.2	Legacy 1, 2, 3, 4	N/A	3.5	Internal Hex
		4.7, 5.2	Legacy 2, 3, 4	N/A	4.5	
		4.7	Legacy 1	N/A	4.5	
	BioHorizons	4.2, 4.6	Tapered Pro	Yellow	3.5	Internal Hex
		4.6	Tapered Plus			
		3.8	Tapered Internal			
		3.0, 3.8	Tapered Tissue Level			
		4.6	Tapered Short			
		4.2	Tapered PTG			
		5.2	Tapered Pro	Green	4.5	
		5.8	Tapered Plus			
		4.6	Tapered Internal			

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
		4.6	Tapered Tissue Level			
		5.8	Tapered Short			
LAA 15°, Implant Logistics, Implant-One 300 Series	Implant Logistics	3.5, 4.1, 4.5	Implant One	300 Series	2.75	Internal Conical 6° Morse Taper
LAA 15°, Implant Logistics, Implant-One 400 Series		4.0, 4.5, 5.5	Implant One	400 Series	3.25	Internal Conical 6° Morse Taper
LAA 15°, BioHorizons Internal Hex	BioHorizons	3.0, 3.4, 3.8	Tapered Plus, Tapered 3.0	3.0 (Gray)	3.0	Internal Hex
LAA 15°, BioHorizons Conical (CONELOG)	BioHorizons	3.3	Tapered Pro Conical	Narrow (Gray)	N/A	Conical
		3.3, 3.8				
		3.8		Regular (Yellow)	N/A	
		3.8, 4.2, 4.6, 5.2				
		4.2, 4.6, 5.2	Tapered Short Conical			
LAA 15°, Implant Direct Legacy 3.0	Implant Direct	3.2	Legacy3 (Blue)	Internal Hex Connection (Blue) 3.0	3.0	Internal Hex
LAA 15°, Hiossen EK	Hiossen	3.3, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0	EK III NH	Hex 2.1	3.35	Internal Hex Conical
LAA 15°, Hiossen ET Mini		3.2, 3.5	ET III Mini	Hex 2.1	2.80	Internal Hex Conical
LAA 15°, Hiossen ET Regular		4.0, 4.5, 5.0 5.5, 6.0, 7.0	ET III Regular, Ultra-Wide	Hex 2.5	3.35	Internal Hex Conical
		4.0, 4.5, 5.0 6.0, 7.0	ET IV Regular, Ultra-Wide			

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 – K260555

LOCATOR Angled Abutment

i. General Information on Submitter

Applicant: Zest Anchors, LLC
Address: 2875 Loker Avenue East
Carlsbad, CA 92010 USA
Telephone: (800) 262-2310
Contact Person: David Lin
Contact Title: Sr. Regulatory Affairs Specialist
Email: regulatoryaffairs@zestdent.com

Date Prepared: April 6, 2026

ii. General Information on Device

Proprietary Name: **LOCATOR Angled Abutment**
Common Name: Dental Implant Abutment
Regulation Number: 21 CFR 872.3630
Classification Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA (Abutment, Implant, Dental, Endosseous)

iii. Predicate Device

Predicate Device	**510(k) Number**
LOCATOR Angled Abutment: Zest Anchors, LLC	K252944
Reference Devices	**510(k) Number**
EK Digital Abutments, Hiossen, Inc.	K233389
ET Hybrid Abutment, Hiossen, Inc.	K170421
ET Abutment System, Hiossen, Inc.	K222636
EK Implants and Abutments System, Hiossen, Inc.	K203360
EK D3.3 and Ultra Wide Implants, Hiossen, Inc.	K240232
ET/SS IMPLANT SYSTEM, Osstem Implant Co., Ltd.	K120847
ET III SA ULTRA WIDE SYSTEM, Hiossen, Inc.	K103537
ETIII SA Fixture System (O3.2mm), Hiossen, Inc.	K153332
ET IV SA Dental Implants, Hiossen, Inc.	K183242
HIOSSEN IMPLANT SYSTEM, Hiossen, Inc.	K140934

iv. Description of Device

The purpose of this submission is to expand the indications of the LOCATOR® Angled Abutment product line to include use with new dental implant systems. This was achieved through collaboration with the implant manufacturer, Hiossen, to prove compatibility of the design of the implant-to-abutment connection, and equivalence of design specification and performance characteristics.

Previously, the LOCATOR Angled Abutment has been cleared by FDA in application K252944 for use with various dental implant systems by the manufacturers BioHorizons and Implant Direct. These LOCATOR Angled Abutments are also designed and cleared for use with removable LOCATOR® Attachment Systems (K072878) and LOCATOR FIXED® (K213391), intended for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants in the mandible or maxilla. This 510(k) submission expands the indications of the LOCATOR Angled Abutment product line with new connections compatible with the following implant systems from Hiossen:

- Hiossen EK (Compatible with LOCATOR Angled Abutment, Hiossen EK)
- Hiossen ET Mini (Compatible with LOCATOR Angled Abutment, Hiossen ET Mini)
- Hiossen ET Regular (Compatible with LOCATOR Angled Abutment, Hiossen ET Regular)
- Hiossen ET Ultra-Wide (Compatible with LOCATOR Angled Abutment, Hiossen ET Regular)

Compatibility of the new LOCATOR Angled Abutments and screws with Hiossen implants has been demonstrated through documented collaboration with the OEM, Hiossen. This was achieved by utilizing the OEM's design specifications, which were shared with Zest to create a LOCATOR Angled Abutment and screw that is equivalent to the implant manufacturer's own abutment device in how it interfaces with their respective implant system(s). Additionally, the LOCATOR Angled Abutment parameters deemed critical to ISO 14801 fatigue testing are also equivalent to the manufacturer's cleared abutment specifications, and therefore do not create a new worst case construct or condition. An equivalent specification is deemed as being identical to or within the OEM's defined specification.

Indication for Use

The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient.

Zest Anchors, LLC. 2875 Loker Avenue East, Carlsbad, CA 92010, USA

IMPLANT COMPATIBILITY

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
LAA 15°, Straumann, BLX	Straumann	3.5, 3.75, 4.0, 4.5	BLX	Regular Base	2.9	Bone Level
		5.0, 5.5, 6.5	BLX	Wide Base	2.9	Bone Level
LAA 15°, Nobel (NP)	Nobel	3.5	NobelActive, NobelParallel CC, NobelReplace CC	Narrow Platform	3.0	Conical
	Implant Direct	3.2, 3.7	InterActive	N/A	3.0	Conical
		3.2, 3.7, 4.2, 4.7	Simply Iconic	N/A	3.0	Conical
LAA 15°, Nobel (RP)	Nobel	4.3	NobelActive, NobelParallel CC, NobelReplace CC	Regular Platform	3.5	Conical
	Implant Direct	4.3, 5.0	InterActive	N/A	3.4	Conical
		4.7, 5.2, 5.7	Simply Iconic	N/A	3.4	Conical
LAA 15°, Neodent (GM)	Neodent	3.5, 3.75, 4.0, 5.0, 6.0	Helix GM	N/A	3.0	Conical / Grand Morse
		3.5, 4.3, 5.0	Drive GM	N/A		Conical / Grand Morse
		3.5, 3.75, 4.0, 5.0	Titamax GM	N/A		Conical / Grand Morse
LAA 15°, TSV	ZimVie	3.7 & 4.1 Green	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	3.5	Internal Hex
		4.7 Purple	Trabecular Metal, Tapered Screw-Vent, Screw-Vent, Advent	N/A	4.5	Internal Hex
	Implant Direct	3.7, 4.2	Legacy 1, 2, 3, 4	N/A	3.5	Internal Hex
		4.7, 5.2	Legacy 2, 3, 4	N/A	4.5	
		4.7	Legacy 1	N/A	4.5	
	BioHorizons	4.2, 4.6	Tapered Pro	Yellow	3.5	Internal Hex
		4.6	Tapered Plus			
		3.8	Tapered Internal			
		3.0, 3.8	Tapered Tissue Level			
		4.6	Tapered Short			
		4.2	Tapered PTG			
		5.2	Tapered Pro	Green	4.5	
		5.8	Tapered Plus			
		4.6	Tapered Internal			
		4.6	Tapered Tissue Level			
		5.8	Tapered Short			
LAA 15°, Implant Logistics, Implant-One 300 Series	Implant Logistics	3.5, 4.1, 4.5	Implant One	300 Series	2.75	Internal Conical 6° Morse Taper

Zest Anchors, LLC. 2875 Loker Avenue East, Carlsbad, CA 92010, USA

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
LAA 15°, Implant Logistics, Implant-One 400 Series		4.0, 4.5, 5.5	Implant One	400 Series	3.25	Internal Conical 6° Morse Taper
LAA 15°, BioHorizons Internal Hex	BioHorizons	3.0, 3.4, 3.8	Tapered Plus, Tapered 3.0	3.0 (Gray)	3.0	Internal Hex
LAA 15°, BioHorizons Conical (CONELOG)	BioHorizons	3.3	Tapered Pro Conical	Narrow (Gray)	N/A	Conical
		3.3, 3.8				
		3.8		Regular (Yellow)	N/A	
		3.8, 4.2, 4.6, 5.2				
		4.2, 4.6, 5.2	Tapered Short Conical			
LAA 15°, Implant Direct Legacy 3.0	Implant Direct	3.2	Legacy3 (Blue)	Internal Hex Connection (Blue) 3.0	3.0	Internal Hex
LAA 15°, Hiossen EK	Hiossen	3.3, 3.5, 4.0, 4.5, 5.0, 5.5, 6.0, 7.0	EK III NH	Hex 2.1	3.35	Internal Hex Conical
LAA 15°, Hiossen ET Mini		3.2, 3.5	ET III Mini	Hex 2.1	2.80	Internal Hex Conical
LAA 15°, Hiossen ET Regular		4.0, 4.5, 5.0 5.5, 6.0, 7.0	ET III Regular, Ultra-Wide	Hex 2.5	3.35	Internal Hex Conical
		4.0, 4.5, 5.0 6.0, 7.0	ET IV Regular, Ultra-Wide			

Zest Anchors, LLC. 2875 Loker Avenue East, Carlsbad, CA 92010, USA

v. Predicate Device Comparison

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

Device Comparison Table

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	Zest Anchors, Inc. LOCATOR Angled Abutment K260555	Zest Anchors, Inc. LOCATOR Angled Abutment K252944	Hiossen, Inc. EK Digital Abutments K233389	Hiossen, Inc. ET Hybrid Abutment K170421	Hiossen, Inc. ET Abutment System (ET Angled) K222636
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	Hiossen connection is compatible with EK connection	Hiossen connection is compatible with ET regular and Ultra-Wide connection	Hiossen connection is compatible with ET Ultra-Wide, ET Regular & ET Mini connection
Indications for Use	The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient. *The complete list of OEM implant compatibilities is provided in the 510(k) Summary.*	The LOCATOR Angled Abutment is indicated for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants to restore masticatory function for the patient. *The complete Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K252944.*	EK DIGITAL ABUTMENTS are intended for use with a dental implant to provide support for prosthetic restorations such as crowns, bridges, or overdentures.	ET Hybrid Abutment is a customized abutment intended for use with HIOSSEN ET dental implant in the edentulous or partially edentulous maxilla or mandible to provide support for prosthetic restorations such as crowns and bridges. All digitally designed copings for use with the ET Hybrid Abutment for CAD/CAM are intended to be sent to a HIOSSEN Inc. manufacturing facility for Manufacture.	The ET Abutments are indicated for use with ET Dental Implants to provide support to prosthetic restoration such as crowns, bridges and overdentures in partially or fully edentulous patients.
Design					
Abutment Cuff Height	2.5 - 7.5 mm	2.5 - 7.5 mm	0.5-8.5mm	0.5~8.0mm	8.0mm
Abutment Type	Angled	Angled	Straight, Angled	Straight, Angled	Angled
Abutment connection	Conical Internal Hex	Conical Internal Hex	Internal Hex	Internal Hex	Conical Internal Hex
Abutment Angle	15°	15°	0°-30°	0°-30°	17°
Sterilization Method	Moist heat end user sterilization	Moist heat end user sterilization	Delivered non-sterilized Steam sterilized by user	Abutments provided sterile	Delivered non-sterilized Steam sterilized by user
Compatibility	Hiossen EK Hiossen ET (Ultra-Wide, Regular, Mini)	BioHorizons (Tapered Plus, Tapered 3.0, Mount Free Tapered Internal, CONELOG Narrow CONELOG Regular Tapered Pro Conical Narrow, Tapered Pro Conical Regular, Tapered Short Conical Regular) Implant Direct Legacy3, 3.0mmD	Hiossen EK	Hiossen ET Regular Hiossen ET Ultra-Wide	Hiossen ET Mini, Hiossen ET Regular, Hiossen ET Ultra-Wide
Materials					

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Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V Zirconia Oxide	Ti-6Al-4V (ASTM F136)
Abutment Coating	TiN	TiN	None	None	None

Zest Anchors, LLC. 2875 Loker Avenue East, Carlsbad, CA 92010, USA

vi. Summary of Non-Clinical Performance Testing

Confirmation of the compatibility of the new Locator Angled Abutments with their corresponding compatible implant systems from Hiossen was based on the requirements provided in the implant manufacturer's drawing specifications, as cleared in their respective 510(k) applications.

No new V&V is required and performance is deemed equivalent to the OEM's FDA cleared device through the replication of critical specifications provided by the implant manufacturer and referenced 510k clearances.

The LOCATOR Angled Abutments are made of titanium alloy Ti-6Al-4V ELI, conforming to ASTM F136, and have a TiN (Titanium Nitride) coating, identical to the predicate device K252944. TiN coating performance was tested per ASTM F1044 and ASTM F1147 in K233587 and being leveraged in the current submission.

The packaging of the LOCATOR Angled Abutments is similar to the packaging of the predicate device, consisting of the LOCATOR angled abutment placed in a vial and sealed in a polybag, along with a parallel post (class I device) used to visually confirm the desired abutment orientation. Additionally, some packaged configurations will include the LOCATOR Angled Abutment Screw packaged in a separate vial and sealed in the same polybag as the abutment and parallel post. Packaging and shipping validation testing was completed previously where the LOCATOR Angled Abutment worst case device and packaging were undamaged after the test, as desired. The results have been leveraged for the LOCATOR Angled Abutment where engineering analysis established that the subject device does not create a new worst-case scenario.

The cleaning and sterilization are identical to the predicate device. The results have been leveraged for the LOCATOR Angled Abutment where engineering analysis established that the subject device does not create a new worst-case scenario.

MR compatibility testing was conducted previously per ASTM F2052-21, ASTM F2213-17, ASTM F2182-19, ASTM F2119-07, and FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment" on abutment and implant components made of Ti-6Al-4V and designed with similar features as the LOCATOR Angled Abutments of this 510(K) submission. The tests that were conducted are Force: static magnetic field induced displacement force, Torque: static magnetic field induced torque, Heating: Radiofrequency field (RF) induced heating, Image Quality: susceptibility induced image artifacts, Heating: Gradient field induced heating, and Vibration: Gradient field induced vibration. The results have been leveraged for the LOCATOR Angled Abutment where engineering analysis established that the subject device does not create a new worst-case scenario.

An assessment for biocompatibility per ISO 10993-1 was conducted previously using testing from K072878 and additional cytotoxicity testing per ISO 10993-5 cleared under K233587. The results have been leveraged for the LOCATOR Angled Abutment where engineering analysis established that the subject device does not create a new worst-case scenario.

Zest Anchors, LLC. 2875 Loker Avenue East, Carlsbad, CA 92010, USA

vii. Substantial Equivalence

As this is a modification to the manufacturer's own cleared and marketed device, the risk based analysis and results of the design control activities performed provide reasonable assurance that the subject devices have demonstrated substantial equivalence to the predicate devices in the that they share the same intended use and principles of operation, use the same materials and manufacturing processes, and utilize the same fundamental design including identical prosthetic attachment features; thus the indications for use has been expanded to include compatibility with additional implant systems from Hiossen. To support this, the following 510(k) numbers are included as reference devices solely to identify the compatible OEM implant bodies K203360, K240232, K120847, K103537, K153332, and K183242.