August 20, 2025

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

Re: K250721
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: July 21, 2025
Received: July 22, 2025

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 systems (QS) regulation (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

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)*

K250721

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			
		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

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 – K250721

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: August 15, 2025

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	K243272
Reference Devices	**510(k) Number**
High Retention Attachment System	K213391
LOCATOR Angled Abutment (Various)	K233587
Screw Vent Implant; Tapered Screw Vent Implant, Sulzer Dental, Inc.	K013227
Tapered Screw-Vent Implant, 4.1mm, Zimmer Dental, Inc.	K072589
NobelActive Internal Connection Implant, Nobel Biocare AB	K071370
Legacy Abutment System, Implant Direct LLC.	K060063
Interactive/ SwishPlus2 Implant System, Implant Direct LLC.	K130572
2014 Interactive/SwishActive system	K143011
Tapered Internal Implant System, BioHorizons Implant Systems, Inc	K071638
BioHorizons Simple Solutions with Laser-Lok®	K100985
BioHorizons Abutments for Zimmer	K103691
BioHorizons CAD/CAM Abutments	K151621
Implant-One System, Implant Logistics, Inc.	K173701

iv. Description of Device

The purpose of this submission is to expand the Indications for Use of the LOCATOR® Angled Abutment product line (K243272 & K233587) by adding compatibility of existing abutments with various new dental implant systems from Implant Direct and Biohorizons. Additionally, the submission expands the Indications for Use of the product line with a modified version of the predicate device shown to be compatible with the Implant Logistics Implant-One Series 300 and Series 400 Implant Systems. The LOCATOR Angled Abutment is designed and intended for the attachment of full or partial, fixed and removable, restorations retained by endosseous implants in the mandible or maxilla, as cleared to be used with LOCATOR FIXED (K213391) and LOCATOR Attachment Systems (K072878).

The expanded Indications for Use of the LOCATOR Angled Abutment demonstrates that:

1. The cleared devices per K243272 are additionally compatible with the following implant systems from Implant Direct and Biohorizons.
   a. The Implant Direct Legacy and Biohorizons Tapered Pro Internal Hex implant systems are compatible with the LOCATOR Angled Abutment Zimmer (ZimVie) TSV 3.5/4.5.
   b. The Implant Direct Simply Iconic and Interactive implant systems are compatible with the LOCATOR Angled Abutment Nobel NP/RP.
2. The LOCATOR® Angled Abutment, Implant Logistics 300 Series, a modified version of the predicate device, is compatible with the Implant Logistics Implant-One System Series 300 implant system.
3. The LOCATOR® Angled Abutment, Implant Logistics 400 Series, a modified version of the predicate device, is compatible with the Implant Logistics Implant-One System Series 400 implant system.

The LOCATOR Angled Abutments are manufactured from titanium (Ti-6Al-4V) and are titanium nitride (TiN) coated in various abutment heights, identical to the predicate device. The LOCATOR Angled Abutment interfacing features are provided at a 15 degree angle to allow for angle correction, substantially equivalent to the predicate device of K233587 and K243272. The abutments will be used with the accessories of the LOCATOR Implant Attachment System (retention inserts, denture attachment housing, and ancillary processing parts) and LOCATOR FIXED Attachment System (fixed inserts, denture attachment housing) for the attachment of a restoration, identical to the predicate device.

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
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

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	Reference Device
	Zest Anchors, Inc. LOCATOR Angled Abutment K25XXXX	Zest Anchors, Inc. LOCATOR Angled Abutment K243272	Implant Direct LLC. LEGACY ABUTMENT SYSTEM, K060063	Implant Direct LLC., INTERACTIVE/ SWISHPLUS2 IMPLANT SYSTEM, , K130572 & 2014 interactive/swishactive system K143011	BioHorizons Implant Systems, INC. Tapered Internal Implant System, K071638 & BIOHORIZONS ABUTMENTS FOR ZIMMER, K103691 & BIOHORIZONS SIMPLE SOLUTIONS WITH LASER-LOK K100985	Implant Logistics, Inc., Implant-One System, , K173701
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	Implant Direct connection is compatible with TSV connection	Implant Direct connection is compatible with NP/RP connection	Biohorizons connection is compatible with TSV connection	Implant-One system, 300, 400 Series 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. *A complete Implant Manufacturer's compatibility table is provided in the Instructions 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 Indications for Use Statement with OEM implant compatibilities is provided in the 510(k) Summary for K243272.*	The Legacy Abutment System is intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns, bridges, or overdentures for edentulous or partially edentulous patients. The Legacy Abutment System is compatible with implants that have mating diameters, lead-in bevels, internal hex sizes, and 1-72UNF internal threads, as shown in the Zimmer Dental Tapered Screw-Vent Surgical Manual. Implant Direct LLC will monitor the compatible implants for modifications to ensure future compatibility. In the event of any modification, Implant Direct LLC will either modify the Legacy	**InterActive/SwishPlus2(K130572):** InterActive/SwishPlus2 Implant System consists of two-piece implants for onestage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Compatibility: InterActive and SwishPlus2 implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform - 3.0mm diameter) and NobelActive™ RP (Regular Platform - 3.4mm diameter) abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform- 3.0mm diameter)	**Tapered Internal Implant System(K071638):** The BioHorizons Tapered Internal Implant System is intended for use in the mandible or maxilla for use as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. The BioHorizons Tapered Internal Implant System may be restored immediately 1) with a temporary prosthesis that is not in functional occlusion or 2) when splinted together for multiple tooth replacement or when stabilized with an overdenture supported by multiple implants. -- **BIOHORIZONS ABUTMENTS FOR ZIMMER(K103691):** BioHorizons Abutments for Zimmer® are abutments that include healing abutments for	The Implant-One™ System is indicated for surgical placement in partially or completely edentulous upper or lower jaws to provide a means for prosthetic attachment to restore a patient's chewing function. The Implant-One™ system is indicated for immediate loading only when primary stability is achieved and with the appropriate occlusal loading.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Zest Anchors, Inc. LOCATOR Angled Abutment K25XXXX	Zest Anchors, Inc. LOCATOR Angled Abutment K243272	Implant Direct LLC. LEGACY ABUTMENT SYSTEM, K060063	Implant Direct LLC., INTERACTIVE/ SWISHPLUS2 IMPLANT SYSTEM, , K130572 & 2014 interactive/swishactive system K143011	BioHorizons Implant Systems, INC. Tapered Internal Implant System, K071638 & BIOHORIZONS ABUTMENTS FOR ZIMMER, K103691 & BIOHORIZONS SIMPLE SOLUTIONS WITH LASER-LOK K100985	Implant Logistics, Inc., Implant-One System, , K173701
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	Implant Direct connection is compatible with TSV connection	Implant Direct connection is compatible with NP/RP connection	Biohorizons connection is compatible with TSV connection	Implant-One system, 300, 400 Series connection
			abutment to ensure compatibility, or cease claiming compatibility to the modified Zimmer Dental Screw-Vent implants.	and NobelActive"' RP (Regular Platform - 3.4mm diameter) (3.5-5.OmmO, 8.5-l8mmLength) implants. Compatibility: InterActive and SwishPlus2 implants are prosthetically compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive"' NP (Narrow Platform - 3.0mm diameter) and NobelActive"' RP (Regular Platform - 3.4mm diameter) abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive"' NP (Narrow Platform- 3.0mm diameter) and NobelActive"' RP (Regular Platform - 3.4mm diameter) (3.5-5.OmmO, 8.5-l8mmLength) implants. -- **interactive/swishactive(K143011):** InterActive/SwishActive Implant System consists of two-piece implants for onestage or two-stage surgical procedures. These implants are intended for use in partially and fully edentulous upper and lower jaws in support of single or multiple-unit restorations and terminal or intermediate abutment support for fixed bridgework. Implants can be indicated for immediate loading when good primary stability has been achieved and with appropriate occlusal loading. Compatibility: InterActive and SwishActive implants are prosthetically	contouring tissue and final restorative abutments to support a prosthesis. The abutments may be used for a single or multiple unit restoration and are compatible for use with BioHorizons Internal and Tapered Internal implant systems and Zimmer® Dental Screw-Vent® and Tapered Screw-Vent® implants with 3.5mm, 4.5mm and 5.7mm internal hex-connection mating platform diameters. BioHorizons Titanium Base Abutments and Laser-Lok Titanium Base Abutments are intended to be used as straight abutments. -- **BIOHORIZONS SIMPLE SOLUTIONS WITH LASER-LOK(K100985):** BioHorizons Simple Solutions with Laser-Lok is an abutment system that includes healing abutments for contouring tissue and final restorative abutments for cementing a prosthesis. The abutment system may be us ed for a single or-multiple unit restoration and is compatible for' use With BioHorizons Internal and Tapered Internal implant Systems and	

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	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Zest Anchors, Inc. LOCATOR Angled Abutment K25XXXX	Zest Anchors, Inc. LOCATOR Angled Abutment K243272	Implant Direct LLC. LEGACY ABUTMENT SYSTEM, K060063	Implant Direct LLC., INTERACTIVE/ SWISHPLUS2 IMPLANT SYSTEM, , K130572 & 2014 interactive/swishactive system K143011	BioHorizons Implant Systems, INC. Tapered Internal Implant System, K071638 & BIOHORIZONS ABUTMENTS FOR ZIMMER, K103691 & BIOHORIZONS SIMPLE SOLUTIONS WITH LASER-LOK K100985	Implant Logistics, Inc., Implant-One System, , K173701
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	Implant Direct connection is compatible with TSV connection	Implant Direct connection is compatible with NP/RP connection	Biohorizons connection is compatible with TSV connection	Implant-One system, 300, 400 Series connection
				compatible with InterActive 3.0 and 3.4mm abutments and Nobel Biocare conical connection NobelActive™ NP (Narrow Platform – 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) titanium abutments. InterActive 3.0 and 3.4mm abutments are prosthetically compatible with Nobel Biocare conical connection NobelActive™ NP (Narrow Platform– 3.0mm diameter) and NobelActive™ RP (Regular Platform – 3.4mm diameter) (3.5- 5.0mmD, 8.5-18mmLength) implants.	Zimmer Dental ScrewVent and Tapered ScrewVent implants with 3.5mm, 4.5mm and 5.7mm internal hex-,connection mating platform diameters.	
Design						
Abutment Cuff Height	2.5 - 7.5 mm	2.5 - 7.5 mm	4.5, 5.7, and 6.5 mm	-	-	0.5-6 mm
Abutment Type	Angled	Angled	Straight, Angled	Straight, Angled	Straight	Straight, Angled
Abutment connection	Internal Hex Conical Conical Taper	TorcFit (Hexalobe) Internal Hex Internal Tri-Channel Conical Grand Morse Taper	Internal hex	Conical	Internal hex	Internal Hex Conical Taper
Abutment Angle	15°	15°	-	15°	-	15°
Sterilization Method	Moist heat end user sterilization	Moist heat end user sterilization	Sterilized by end user	Non-sterile inside a vial sealed with a cap	Abutments provided sterile	-

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device	Reference Device
	Zest Anchors, Inc. LOCATOR Angled Abutment K25XXXX	Zest Anchors, Inc. LOCATOR Angled Abutment K243272	Implant Direct LLC. LEGACY ABUTMENT SYSTEM, K060063	Implant Direct LLC., INTERACTIVE/ SWISHPLUS2 IMPLANT SYSTEM, , K130572 & 2014 interactive/swishactive system K143011	BioHorizons Implant Systems, INC. Tapered Internal Implant System, K071638 & BIOHORIZONS ABUTMENTS FOR ZIMMER, K103691 & BIOHORIZONS SIMPLE SOLUTIONS WITH LASER-LOK K100985	Implant Logistics, Inc., Implant-One System, , K173701
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	Implant Direct connection is compatible with TSV connection	Implant Direct connection is compatible with NP/RP connection	Biohorizons connection is compatible with TSV connection	Implant-One system, 300, 400 Series connection
Compatibility	Zimmer (ZimVie) TSV 3.5ZimVie TSV 3.5 Zimmer (ZimVie)TSV 4.5 Nobel RP Nobel NP Neodent Grand Morse Implant Direct Legacy Implant Direct InterActive Implant Direct Simply Biohorizons (Tapered Internal Implant System & LASER-LOK) Iconic Implant-One system, 300&400 series	Straumann BLX Zimmer (ZimVie) TSV 3.5ZimVie TSV 3.5 Zimmer (ZimVie)TSV 4.5 Nobel RP Nobel NP Neodent Grand Morse	Implant Direct Legacy	Implant Direct InterActive Implant Direct Simply Iconic	Biohorizons (Tapered Internal Implant System & LASER-LOK)	Implant One System, (300&400series)
Materials						
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Titanium 6AL4V ELI	Titanium alloy	Titanium alloy	Titanium alloy (Ti-6Al-4V ELI)
Abutment Coating	TiN	TiN	-	-	-	-

vi. Summary of Non-Clinical Performance Testing

The critical features were identified on the OEM component specifications (implant connections, abutment connections, and abutment fixation screws specifications), which are required for proper function. Using engineering analysis, critical areas for implant engagement were analyzed using the implant drawing, abutment drawing and/or the abutment screw drawings provided by the manufacturer. Using the data collected, including the variations, the specifications for the design were created. These specifications were reviewed for manufacturability. All critical tolerances were verified functionally in OEM implants.

Fatigue testing according to ISO 14801: 2016 was performed for the tallest abutment cuff height LOCATOR Angled Abutment along with the smallest diameter OEM implant for the predicate devices cleared in K243272. Compatibility of the predicate LOCATOR Angled Abutment with the various implant systems from Implant Direct and Biorizons, was conducted through engineering analysis, cooperatively with the implant manufacturer (OEM). The LOCATOR Abutments for Implant Logistics ONE 300/400 Series implants have been designed according to the manufacturer's specifications. This abutment design including the implant connection has been cleared per Implant Logistics 510(k) (K173701 and K102822), which required ISO 14801 testing in order to approve the worst conditions, for cuff height and connection. As the LOCATOR connection is identical to the specifications provided by the OEM, the design of the LOCATOR Abutments for Implant Logistics ONE 300/400, a modification of the predicate device, does not create a new worst case.

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 K233587 and K243272. 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. Packaging and shipping validation testing was completed where the LOCATOR Angled Abutment worst case device and packaging were undamaged after the test, as desired.

The cleaning and sterilization are identical to the predicate device cleared under K233587 and K243272. 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 using testing from K072878 and additional cytotoxicity testing per ISO 10993-5 cleared under K233587 was provided in this submission. 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.

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

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 Implant Direct, Biohorizons, and Implant One.

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