October 15, 2025

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

Re: K252944
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: September 5, 2025
Received: September 15, 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

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*

K252944

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			

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

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 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, Mount Free Tapered Internal	3.0 (Gray)	3.0	Internal Hex
LAA 15°, BioHorizons Conical	BioHorizons (Camlog)	3.3	CONELOG	Narrow (Gray)	N/A	Conical
		3.3, 3.8	Tapered Pro Conical			
		3.8	CONELOG	Regular (Yellow)	N/A	
		3.8, 4.2, 4.6, 5.2	Tapered Pro Conical			
		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

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 – K252944

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:	October 09, 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	K250721
Reference Devices	**510(k) Number**
BioHorizons CAD/CAM Abutments, BioHorizons Implant Systems, Inc.	K151621
Tapered Pro Conical Implant System , BioHorizons Implant Systems, Inc.	K240187
Legacy and Custom InterActive Titanium Abutments, Implant Direct LLC.	K192218

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 manufacturers BioHorizons and Implant Direct 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 applications K233587, K243272, and K250721 for use with various dental implant systems by the manufacturers BioHorizons, Implant Direct, Implant Logistics, Neodent, Nobel Biocare, Straumann, and ZimVie (Zimmer). 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 BioHorizons (Camlog) and Implant Direct.

- BioHorizons Tapered 3.0 (Internal Hex)
- BioHorizons Tapered Pro Conical Narrow platform (CONELOG)
- BioHorizons Tapered Pro Conical Regular platform (CONELOG)
- BioHorizons Tapered Short Conical Regular platform (CONELOG)
- Implant Direct Legacy 3, 3.0mmD

Compatibility of the new LOCATOR Angled Abutments and screws with either the BioHorizons or Implant Direct implants has been demonstrated through documented collaboration with the OEM. 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
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

Zest Model	Implant Mfg	Implant Diameters (Ø) mm	Implant System Name	Implant Platform Name	Platform Diameter (Ø) mm	Connection Type
LAA 15°, BioHorizons Internal Hex	BioHorizons	3.0, 3.4, 3.8	Tapered Plus, Tapered 3.0, Mount Free Tapered Internal	3.0 (Gray)	3.0	Internal Hex
LAA 15°, BioHorizons Conical	BioHorizons (Camlog)	3.3	CONELOG	Narrow (Gray)	N/A	Conical
		3.3, 3.8	Tapered Pro Conical			
		3.8	CONELOG	Regular (Yellow)	N/A	
		3.8, 4.2, 4.6, 5.2	Tapered Pro Conical			
		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

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 K252944	Zest Anchors, Inc. LOCATOR Angled Abutment K250721	BioHorizons Implant Systems, INC. BioHorizons CAD/CAM Abutments K151621	BioHorizons Implant Systems, INC. Tapered Pro Conical Implant System K240187	Implant Direct LLC. Custom Legacy and Custom InterActive Titanium Abutments , K192218
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	BioHorizons connection is compatible with Tapered Plus, Tapered 3.0, Mount Free Tapered Internal, CONELOG, and Tapered Pro Conical connection	BioHorizons connection is compatible with CONELOG, Tapered Short and Tapered Pro Conical connection	Implant Direct connection is compatible with legacy3, 3.0mmD 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 K250721.*	BioHorizons CAD/CAM Abutments are dental abutments placed onto a dental implant to provide support for dental prosthetic restorations. The abutments include: 1) Titanium abutment blanks with a pre-machined implant connection where the upper portion may be custom-milled in accordance with a patient-specific design using CAD/CAM techniques; and 2) Titanium bases with a pre-machined implant connection upon which a CAD/CAM designed superstructure may be fitted to complete a two-piece dental abutment. The abutments include an abutment screw for fixation to the underlying implant. The abutments may be used for single-unit (single-tooth) or multiple-unit (bridges and bars) restorations 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. All digitally designed abutments and/or copings for use with BioHorizons CAD/CAM Abutments are intended to	BioHorizons Tapered Pro Conical dental implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. These dental implants 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 Tapered Short Conical dental implants are intended for use in the mandible or maxilla as an artificial root structure for single tooth replacement or for fixed bridgework and dental retention. These dental implants must be restored using delayed loading, for single tooth replacement, or may be used with a terminal or intermediate abutment for fixed or removable bridgework or for overdentures. Tapered Short Conical implants should be used only when there is not enough space for a longer implant. If the ratio of crown length to implant length is	Custom Titanium Abutments are customizable devices intended for use with dental implants in the maxillary and/or mandibular arches to provide support for crowns or bridges for edentulous or partially edentulous patients. • Custom Titanium Abutment for narrow (3.2mmD, 3.3mmD) implants: Indicated for single-tooth replacement of mandibular central and lateral incisors and maxillary lateral incisors. Also indicated for multiple tooth replacements. • Custom Titanium Abutment for short (8mm) 3.7mmD implants: Indicated for tooth replacement of mandibular and maxillary central and lateral incisors.

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	Zest Anchors, Inc. LOCATOR Angled Abutment K252944	Zest Anchors, Inc. LOCATOR Angled Abutment K250721	BioHorizons Implant Systems, INC. BioHorizons CAD/CAM Abutments K151621	BioHorizons Implant Systems, INC. Tapered Pro Conical Implant System K240187	Implant Direct LLC. Custom Legacy and Custom InterActive Titanium Abutments , K192218
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	BioHorizons connection is compatible with Tapered Plus, Tapered 3.0, Mount Free Tapered Internal, CONELOG, and Tapered Pro Conical connection	BioHorizons connection is compatible with CONELOG, Tapered Short and Tapered Pro Conical connection	Implant Direct connection is compatible with legacy3, 3.0mmD connection
			be sent to a BioHorizons-validated milling center for manufacture. BioHorizons abutments designed using CAD/CAM techniques must fulfill the BioHorizons allowable range of design parameters.	unfavorable, the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional. BioHorizons conical dental prosthetic components connected to the endosseous dental implants are intended for use as an aid in prosthetic rehabilitations of the maxillary or mandibular arch to provide support for prosthetic restorations. All digitally designed abutments for use with Conical CAD/CAM Ti Blanks and Ti Bases are to be sent to a BioHorizons validated milling center for manufacture.	
Design					
Abutment Cuff Height	2.5 - 7.5 mm	2.5 - 7.5 mm	0-12.1mm	0.5mm Min.	-
Abutment Type	Angled	Angled	Straight, Angled	Straight, Angled	Straight, Angled
Abutment connection	Conical Internal Hex	TorcFit (Hexalobe) Internal Hex Internal Tri-Channel Conical Grand Morse Taper Conical Conical Taper	Internal hex	Conical	Internal hex
Abutment Angle	15°	15°	0°-30°	0°-30°	Maximum angle of 30° from the axis of the implant
Sterilization Method	Moist heat end user sterilization	Moist heat end user sterilization	N/A; provided non-sterile, steam sterilization in accordance with qualified cycles as specified in the Instructions for Use	Non-sterile	Sold non-sterile, Steam sterilization by end user

	Subject Device	Primary Predicate Device	Reference Device	Reference Device	Reference Device
	Zest Anchors, Inc. LOCATOR Angled Abutment K252944	Zest Anchors, Inc. LOCATOR Angled Abutment K250721	BioHorizons Implant Systems, INC. BioHorizons CAD/CAM Abutments K151621	BioHorizons Implant Systems, INC. Tapered Pro Conical Implant System K240187	Implant Direct LLC. Custom Legacy and Custom InterActive Titanium Abutments , K192218
Reason for Predicate/Reference	n/a	Design of Locator Angled Abutment	BioHorizons connection is compatible with Tapered Plus, Tapered 3.0, Mount Free Tapered Internal, CONELOG, and Tapered Pro Conical connection	BioHorizons connection is compatible with CONELOG, Tapered Short and Tapered Pro Conical connection	Implant Direct connection is compatible with legacy3, 3.0mmD connection
Compatibility	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	Straumann BLX Zimmer (ZimVie) 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	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	BioHorizons CONELOG Narrow CONELOG Regular Tapered Pro Conical Narrow, Tapered Pro Conical Regular, Tapered Short Conical Regular	Implant Direct Legacy3, 3.0mmD
Materials					
Abutment	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V ELI
Abutment Coating	TiN	TiN	Anodized, None	Anodized, None	-

vi. Summary of Non-Clinical Performance Testing

Confirmation of the compatibility of the new Locator Angled Abutments with their corresponding compatible implant systems from BioHorizons and Implant Direct was based on the requirements provided in the implant manufacturer's drawing specifications, as cleared in their respective 510(k) applications. The critical features were identified on the OEM component specifications (abutment-to-implant connection specifications and abutment fixation screws specifications), which are required for proper function. Using engineering analysis, critical areas for abutment-to-implant engagement were evaluated using the abutment and abutment screw drawings, provided by the manufacturers, and all critical tolerances functionally verified with the OEM implant.

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 K250721. 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 configuration 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 cleared under K250721. 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.

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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.

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 and BioHorizons.

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