July 22, 2020

Elegant Dental Corp.
% Floyd Larson
President
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K200355
Trade/Device Name: Duranext Abutments
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: June 18, 2020
Received: June 22, 2020

Dear Floyd Larson:

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,

for Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K200355

Device Name
Duranext Abutments

Indications for Use *(Describe)*

Duranext Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Implant Body Diameter, mm	Implant Platform
NobelActive® (conical connection)	3.0	3.0 (3.0 mm)
	3.5	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
NobelReplace Conical Connection	3.5	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
NobelParallel Conical Connection	3.75	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
NobelReplace® (Internal tri-channel)	3.5	NP (3.5 mm)
	4.3	RP (4.3 mm)
	5.0	WP (5.0 mm)
	6.0	6.0 (6.0 mm)
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.7, 4.1	3.5 mm
	4.7	4.5 mm
	6.0	5.7 mm

All digitally designed custom abutments for use with Duranext Abutments are to be sent to an Elegant Direct Corp. validated milling center for manufacture.

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

Duranext Abutments
Elegant Direct Corp.

July 21, 2020

ADMINISTRATIVE INFORMATION

Manufacturer Name	Elegant Direct Corp. 2308 McDonald Avenue Brooklyn, NY 11223 Telephone: +1-718-375-5999 Fax: +1-718-375-5983
Official Contact	Gary Fingerman, President
Representative/Consultant	Floyd G. Larson, MS, MBA Kevin A. Thomas, PhD PaxMed International, LLC 12264 El Camino Real, Suite 400 San Diego, CA 92130 Telephone: +1 858-792-1235 Fax: +1 858-792-1236 Email: flarson@paxmed.com kthomas@paxmed.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	Duranext Abutments
Common Name	Dental implant abutment
Classification Name	Endosseous dental implant abutment
Classification Regulations	21 CFR 872.3630, Class II
Product Code	NHA
Classification Panel	Dental Products Panel
Reviewing Division	DHT1B: Division of Dental Devices

PREDICATE DEVICE INFORMATION

Primary predicate device:	K150203 Medentika CAD/CAM Abutments, Medentika GmbH
Reference devices:	K160784 CAM Titanium Blanks, Altatec GmbH
	K171799 Elos Accurate Customized Abutment, Elos Medtech Pinol A/S
	K134045 Zimmer Zfx Ti Abutment for NobelActive, NobelReplace CC, Zimmer Dental Inc.

K183518, Preat Abutments, Preat Corporation
K071370, NobelActive Internal Connection Implant, Nobel Biocare AB
K142260, NobelActive®, Nobel Biocare AB
K102436, NobelActive 3.0, Nobel Biocare AB
K062566, NobelReplace Tapered Conical Connection, Nobel Biocare USA LLC
K173418, NobelParallel™ Concial Connection, Nobel Biocare AB
K050258, Groovy Implants, Nobel Biocare AB
K011028, Screw-Vent Dental Implant System, Sulzer Dental, Inc.
K112160, Tapered Screw-Vent® X Implant, Zimmer Dental, Inc.

INDICATIONS FOR USE STATEMENT

Duranext Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.

Implant System Compatibility	Implant Body Diameter, mm	Implant Platform
NobelActive® (conical connection)	3.0	3.0 (3.0 mm)
	3.5	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
NobelReplace Conical Connection	3.5	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
NobelParallel Conical Connection	3.75	NP (3.5 mm)
	4.3, 5.0	RP (3.9 mm)
	5.5	WP (5.1 mm)
NobelReplace® (Internal tri-channel)	3.5	NP (3.5 mm)
	4.3	RP (4.3 mm)
	5.0	WP (5.0 mm)
	6.0	6.0 (6.0 mm)
Zimmer Screw Vent®/ Tapered Screw-Vent®	3.7, 4.1	3.5 mm
	4.7	4.5 mm
	6.0	5.7 mm

All digitally designed custom abutments for use with Duranext Abutments are to be sent to an Elegant Direct Corp. validated milling center for manufacture.

SUBJECT DEVICE DESCRIPTION

Duranext Abutments from Elegant Direct Corp. are a line of machinable blanks incorporating interface features compatible with eleven (11) endosseous dental implant system platforms (three (3) designs from two (2) manufacturers) and intended to be milled at an Elegant Direct Corp. validated milling center to produce patient-specific dental implant abutments. The subject device platform diameters range from 3.0 mm to 6.0 mm, and the corresponding compatible implant body diameters range from 3.0 mm to 6.0 mm.

Duranext Abutments are designed for fabrication of custom titanium alloy dental implant abutments by a CAD/CAM process. All patient-specific custom abutment fabrication is by prescription on the order of the clinician. The portion of each abutment available for milling is 9.5 mm in diameter and 20 mm long. The apical end is premanufactured to fit the compatible implant platform, as shown above, and is available in an engaging (anti-rotation) design. A feature at the coronal end of the abutment is provided to interface with the milling equipment. Each abutment is provided with a screw designed to fit the compatible implant. The patient-specific abutment is intended to support a cement-retained single crown or multi-unit restoration.

The design parameters for the CAD/CAM fabrication of custom abutments from Duranext Abutment are:

Minimum wall thickness – 0.5 mm
Minimum post height – 4.0 mm
Maximum abutment height from the prosthetic platform – 20.0 mm
Maximum gingival height – 4.0 mm
Minimum gingival height – 0.5 mm
Angulation – 0° to 30°

Manufacture of CAD/CAM custom abutments from Duranext Abutments is to be performed at an Elegant Direct Corp. validated milling center that is registered with FDA as a medical device manufacturing establishment.

PERFORMANCE DATA

Non-clinical data submitted to demonstrate substantial equivalence included: sterilization validation according to ISO 17665-1; biocompatibility according to ISO 10993-5 and ISO 10993-12; reverse engineering of OEM implant bodies, OEM abutments, and OEM abutment screws to confirm compatibility; and static compression and compression fatigue testing according to ISO 14801. No clinical data were included in this submission.

EQUIVALENCE TO MARKETED DEVICES

The subject device is substantially equivalent in indications and design principles to the primary predicate device and the reference devices listed above. Provided at the end of this summary are tables comparing the Indications for Use Statements and the technological characteristics of the subject device, the primary predicate device, and the reference devices.

With regard to intended use, the subject Duranext Abutment is substantially equivalent to the primary predicate device, K150203 Medentika CAD/CAM Abutments and to the abutment reference devices K160784 CAM Titanium Blanks, K171799 Elos Accurate Customized Abutment and K134045 Zimmer Zfx Ti Abutment for NobelActive, NobelReplace CC. All are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient. While the primary predicate device is intended for use with the Straumann CARES System, digitally designed abutments for use with the abutment reference devices are intended to be sent to a validated milling center for manufacture, as is the case for the subject device. With regard to OEM implant system compatibility, all subject device compatibilities are included in those for the primary predicate device, with the exception of the WP (5.5) platform of the NobelActive and NobelParallel Conical Connection implants. Slight differences in the wording of the Indications for Use do not affect the intended use of the device to support a single-tooth or multiple-unit prosthesis for restoration of chewing function.

With regard to design, the subject device, the primary predicate device and abutment reference devices all are titanium alloy blanks intended to be used for the manufacture of patient-specific abutments using CAD/CAM techniques, with manufacture of the final finished device performed at a validated milling center – an Establishment that is registered with FDA as a manufacturer. The design parameters intended for the subject device are substantially equivalent to those of the primary predicate device; maximum angulation for each is 30°, maximum abutment height is 20 mm and minimum post height is 4 mm, maximum gingival height for the subject

device is 4 mm, which is not a worse case than the 6 mm maximum gingival height of the primary predicate device.

Testing to support substantial equivalence included biocompatibility testing according to ISO 10993-1, ISO 10993-5 and ISO 10993-12. In addition, performance testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* was performed to demonstrate that the subject device has sufficient strength for its intended use when tested in dynamic loading.

CONCLUSION

The subject device, the primary predicate device, and the abutment reference devices have the same intended use, have similar technological characteristics, and are made of the same materials. The subject device, the primary predicate, and reference devices encompass the same range of physical dimensions, are packaged in similar materials, and are to be sterilized using similar methods. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Device Comparison Table of Substantial Equivalence – Indications for Use Statements

<table>
<tr><th>Subject Device</th><th></th></tr>
<tr><td>Duranext Abutments
Elegant Direct Corp.</td><td>Duranext Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient
<table>
<tr><th>Implant System Compatibility</th><th>Implant Body Diameter, mm</th><th>Implant Platform</th></tr>
<tr><td rowspan="4">NobelActive® (conical connection)</td><td>3.0</td><td>3.0 (3.0 mm)</td></tr>
<tr><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3, 5.0</td><td>RP (3.9 mm)</td></tr>
<tr><td>5.5</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="2">NobelReplace Conical Connection</td><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3, 5.0</td><td>RP (3.9 mm)</td></tr>
<tr><td rowspan="3">NobelParallel Conical Connection</td><td>3.75</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3, 5.0</td><td>RP (3.9 mm)</td></tr>
<tr><td>5.5</td><td>WP (5.1 mm)</td></tr>
<tr><td rowspan="4">NobelReplace® (Internal tri-channel)</td><td>3.5</td><td>NP (3.5 mm)</td></tr>
<tr><td>4.3</td><td>RP (4.3 mm)</td></tr>
<tr><td>5.0</td><td>WP (5.0 mm)</td></tr>
<tr><td>6.0</td><td>6.0 (6.0 mm)</td></tr>
<tr><td rowspan="3">Zimmer Screw Vent®/
Tapered Screw-Vent®</td><td>3.7, 4.1</td><td>3.5 mm</td></tr>
<tr><td>4.7</td><td>4.5 mm</td></tr>
<tr><td>6.0</td><td>5.7 mm</td></tr>
</table>
All digitally designed custom abutments for use with Duranext Abutments are to be sent to an Elegant Direct validated milling center for manufacture.</td></tr>
<tr><th>Primary Predicate Device</th><th></th></tr>
<tr><td>K150203
Medentika CAD/CAM Abutments (Preface)
Medentika GmbH</td><td>Medentika Preface CAD/CAM Abutments are intended for use with dental implants as a support for single or multiple tooth prostheses in the maxilla or mandible of a partially or fully edentulous patient.
<table>
<tr><th>Implant System Compatibility</th><th>Series</th><th>Implant Diameter (mm)</th><th>Platform Diameter (mm)</th></tr>
<tr><td>Nobel Biocare Replace™ Select</td><td>E</td><td>3.5, 4.3, 5.0, 6.0</td><td>3.5, 4.3, 5.0, 6.0</td></tr>
<tr><td>Nobel Biocare NobelActive™</td><td>F</td><td>3.0, 3.5, 4.3, 5.0</td><td>3.0, 3.5, 3.9 (4.3), 3.9 (5.0)</td></tr>
<tr><td>Biomet 3i Osseotite® Certain®</td><td>H</td><td>3.25, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Biomet 3i Osseotite®</td><td>I</td><td>3.25, 3.75, 4.0, 5.0</td><td>3.4, 4.1, 5.0</td></tr>
<tr><td>Nobel Biocare Brånemark</td><td>K</td><td>3.3, 3.75, 4.0, 5.0</td><td>3.5, 4.1, 4.1, 5.1</td></tr>
<tr><td>Straumann Bone Level</td><td>L</td><td>3.3, 4.1, 4.8</td><td>3.3, 4.1, 4.8</td></tr>
<tr><td>Straumann Standard</td><td>N</td><td>3.3, 4.1, 4.8</td><td>3.5(NNC), 4.8, 6.5</td></tr>
<tr><td>Zimmer Tapered Screw-vent®</td><td>R</td><td>3.3, 3.7, 4.1, 4.7, 6.0</td><td>3.5, 4.5, 5.7</td></tr>
<tr><td>Astra Tech OsseoSpeed™</td><td>S</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td><td>3.0, 3.5, 4.0, 4.5, 5.0</td></tr>
<tr><td>Dentsply Friadent® Frialit/XiVE®</td><td>T</td><td>3.4, 3.8, 4.5, 5.5</td><td>3.4, 3.8, 4.5, 5.5</td></tr>
</table>
Medentika PreFace is intended for use with the Straumann® CARES® System. All digitally designed abutments for use with Medentika CAD/CAM Abutments are intended to be manufactured at a Straumann® CARES® validated milling center</td></tr>
</table>

<table>
<tr><th>Reference Devices</th><th></th></tr>
<tr><td>K160784
CAM Titanium Blanks
Altatec GmbH</td><td>CAM Titanium Blanks are intended for the fabrication of abutments and healing caps on CAMLOG® SCREWLINE and CAMLOG® ROOT-LINE [, on CONELOG SCREWLINE or on iSy] implants in the maxilla and mandible for the purpose of supporting single or multiple tooth prostheses of a partially or fully edentulous patient. Digitally designed abutments fabricated with CAD/CAM techniques for use with CAMLOG® CAM Titanium Blanks are intended to be sent to a CAMLOG validated milling center for manufacture.</td></tr>
<tr><td>K171799
Elos Accurate® Customized Abutment
Elos Medtech Pinol A/S</td><td>The Elos Accurate® Customized Abutments are intended for attaching to dental implants in order to provide basis for single or multiple tooth prosthetic restorations. The Elos Accurate® Customized Abutment will be attached to a dental implant using the included Elos Prosthetic screw. The Elos Accurate® Customized Abutments are compatible with the following implant systems:
<table>
<tr><th>Ref. No.</th><th>Platform compatibility</th><th>Implant diameter</th></tr>
<tr><td>AB-BRA411213-US</td><td>Nobel Biocare® / Brånemark® RP</td><td>3.75 mm & 4 mm</td></tr>
<tr><td>AB-BRA351213-US</td><td>Nobel Biocare® / Brånemark® NP</td><td>3.3 mm</td></tr>
<tr><td>AB-BRA511213-US</td><td>Nobel Biocare® / Brånemark® WP</td><td>5 mm</td></tr>
</table>
All digitally designed Elos Accurate® Customized Abutments are intended to be manufactured at an Elos Medtech approved milling facility.</td></tr>
<tr><td>K134045
Zimmer Zfx Titanium Abutment for NobelActive Implant System
Zimmer Dental Inc.</td><td>The Zimmer Zfx Titanium Abutment for NobelActive Implant System is designed for use as a terminal or intermediate abutment for cement retained prostheses. The abutment can be used with NobelActive and NobelReplace Conical Connection implants with a Narrow Platform (NP) Ø 3.5mm or a Regular Platform (RP) Ø 3.9mm.</td></tr>
</table>

Device Comparison Table of Substantial Equivalence – Technological Characteristics

Comparison	Subject Device	Primary Predicate Device	Reference Devices		
	Duranext Abutments Elegant Direct Corp.	K150203 Medentika CAD/CAM Abutments (Preface) Medentika GmbH	K160784 CAM Titanium Blanks Altatec GmbH	K171799 Elos Accurate® Customized Abutment Elos Medtech Pinol A/S	K134045 Zimmer Zfx Titanium Abutment for NobelActive Implant System Zimmer Dental Inc.
Design					
Abutment Blank	CAD/CAM Blank	CAD/CAM Blank	CAD/CAM Blank	CAD/CAM Blank	CAD/CAM Blank
CAD/CAM Abutment Design Parameters					
Minimum post height, mm	4	4	Not stated	Not stated	3
Maximum gingival height, mm	4	6	Not stated	Not stated	Not stated
Maximum abutment height, mm	20	20	Not stated	Not stated	12
Maximum abutment angulation	30°	30°	30°	20°	25°
Abutment attachment to implant	Screw	Screw	Screw	Screw	Screw
Prosthesis attachment to abutment	Cement	Cement	Cement	Cement	Cement
Restoration	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit	Single-unit, Multi-unit
Abutment/implant platform diameter, mm	3.0 – 5.7	3.0 – 6.0	3.3 – 6.0	3.5 – 5.1	3.5, 3.9
Abutment/ Implant Interface	Internal	Internal	Internal	External	Internal
Material					
Abutment	Ti-6Al-4V ELI	Ti alloy	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti-6Al-4V
Screw	Ti-6Al-4V ELI	Ti alloy	Ti-6Al-4V ELI	Ti-6Al-4V ELI	Ti alloy