September 29, 2020

Altatec GmbH
% Bill Hornbuckle
Regulatory Affairs Associate II
BioHorizons Implant Systems, Inc.
2300 Riverchase Center
Birmingham, Alabama 35244

Re: K193401
Trade/Device Name: Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: August 28, 2020
Received: August 31, 2020

Dear Bill Hornbuckle:

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)*
K193401

Device Name
Altatec GmbH CAMLOG® / CONELOG® PROGRESSIVE-LINE Implants

Indications for Use *(Describe)*

CAMLOG®/CONELOG® PROGRESSIVE-LINE implants are intended for the restoration of edentulous and partially edentulous jaws with prosthetic restorations such as implant-supported single crowns, bridges and full dentures.
Specifically for:
- single-tooth gaps,
- partially edentulous jaws with several missing teeth or
- edentulous jaws.

CAMLOG®/CONELOG® PROGRESSIVE-LINE implants are suitable for oral endosseous implantation in the maxillary and/or mandibular bone and are intended for immediate or delayed implantation. They are indicated for transgingival healing (one-stage, using healing caps or abutments) or subgingival healing (two-stage, using cover screws). If single-phase healing is intended, the implants can be loaded immediately if the primary stability achieved is adequate for functional loading. In conjunction with the corresponding abutments, the implants can be used for screw-retained or cemented restorations such as single crowns, bridges and full dentures.

CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants with a diameter of 3.3 mm have the following additional specific indications:
Implants with a diameter of 3.3 mm are indicated as an alternative in cases where the alveolar ridge width is only 5–6 mm. Because of their lower tensile strength compared with larger diameter implants, they should only be used under the following conditions:
- As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors.
- An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal extensions.
- Implants of Ø 3.3 mm are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account.
- Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø 3.3 mm implants.
- The healing time for diameter 3.3 mm implants is at least 12 weeks.

CONELOG® implants with 7 mm length have the following additional specific indications:
These Implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional.

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
21 CFR 807.92

Submitter's Name & Address

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Official contact: Reto Pusterla, Head, Regulatory Affairs
Date prepared: September 29 2020

Application Correspondent's Name & Address

Correspondent: BioHorizons Implant Systems, Inc.
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Birmingham, AL 35244
Phone (205) 967-7880
Fax (205) 870-0304
Official contact: Bill Hornbuckle, Regulatory Affairs Associate II
Date prepared: September 29 2020

Name of the Device

Trade Name: Altatec GmbH CAMLOG® / CONELOG® PROGRESSIVE-LINE Implants
Common or Usual Name: Screw-type dental implant
Classification Name: Endosseous dental implant
Classification Number: Class II (21 CFR 872.3640)

Predicate Devices

Primary Predicate Device:

- K113779, Altatec GmbH CONELOG® Implant System, December 14, 2012

Reference Predicate Device:

- K083496, Altatec GmbH CAMLOG® Implant System Modified Implants and Abutments, January 30, 2009

Device Description

The CONELOG® PROGRESSIVE-LINE Implants and the CAMLOG® PROGRESSIVE-LINE Implants represent an extension of the range of implants which are based on the well-documented technology used for implants offered by CAMLOG Biotechnologies GmbH / Altatec GmbH.

Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are titanium (CPTi Grade 4), screw-form endosseous dental implants and have a conical outer geometry in the apical area. The outer implant surface is abrasive-blasted and acid-etched – medium rough surface (Promote® surface structure). The implant shoulder of the CONELOG®/CAMLOG® PROGRESSIVE-LINE implants is machined. CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are supplied in different diameters and lengths (See Table 1. below).

Implant	Diameter	Length
CONELOG® PROGRESSIVE-LINE Promote® plus	3.3 mm	9/11/13/16 mm
	3.8/4.3/5.0 mm	7/9/11/13/16 mm
CAMLOG® PROGRESSIVE-LINE Promote® plus	3.3 mm	11/13/16 mm
	3.8/4.3/5.0 mm	9/11/13/16 mm

Table 1.

NOTE: The term PROGRESSIVE-LINE refers to the implant body shape, whereas the terms CONELOG® or CAMLOG® refer to the implant-abutment connection designs.

The Altatec GmbH CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are placed surgically in the maxillary and/or mandibular bone and serve as anchors for functional and esthetic oral rehabilitations in partially and fully edentulous patients. The prosthetic rehabilitation is carried out with single crowns, bridges, or full arch prostheses, which are fastened to the implants by corresponding secondary parts (i.e. abutments).

The implant-abutment connection consists either of a Tube-in-Tube™ configuration with three cams for abutment positioning and rotational stability (CAMLOG® PROGRESSIVE-LINE) or an inner conical section and an indexing section with three cams for abutment positioning and as an antirotational mechanism (CONELOG® PROGRESSIVE-LINE). This means that the respective implant-abutment connections are identical to the connections of the respective equivalent systems (i.e. CONELOG®/CAMLOG® prosthetic product lines).

CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are intended for one stage (transgingival / non-submerged) or two stage (submerged) protocols. The CONELOG® PROGRESSIVE-LINE implants are placed at bone level (epicrestally) and the CAMLOG® PROGRESSIVE-LINE implants are placed 0.4mm supracrestally. The CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are made of the same implant grade material as the predicate devices (commercially pure titanium, CPTi Grade 4, meeting the requirements of ASTM F67-13, *Standard Specification for Unalloyed Titanium for Surgical Implant Applications*).

The product is packaged using materials known in the industry to be appropriate for medical device packaging and is provided with a minimum sterility assurance level of 10^{-6}, validated in compliance with ISO 11137-1 *Sterilization of healthcare products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices.*

Indications for Use

CAMLOG®/CONELOG® PROGRESSIVE-LINE implants are intended for the restoration of edentulous and partially edentulous jaws with prosthetic restorations such as implant-supported single crowns, bridges and full dentures. Specifically for:

- single-tooth gaps,
- partially edentulous jaws with several missing teeth or
- edentulous jaws.

CAMLOG®/CONELOG® PROGRESSIVE-LINE implants are suitable for oral endosseous implantation in the maxillary and/or mandibular bone and are intended for immediate or delayed implantation. They are indicated for transgingival healing (one-stage, using healing caps or abutments) or subgingival healing (two-stage, using cover screws). If single-phase healing is intended, the implants can be loaded immediately if the primary stability achieved is adequate for functional loading. In conjunction with the corresponding abutments, the implants can be used for screw-retained or cemented restorations such as single crowns, bridges and full dentures.

CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants with a diameter of 3.3 mm have the following additional specific indications:

Implants with a diameter of 3.3 mm are indicated as an alternative in cases where the alveolar ridge width is only 5–6 mm. Because of their lower tensile strength compared with larger diameter implants, they should only be used under the following conditions:

- As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors.
- An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal extensions.
- Implants of Ø 3.3 mm are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account.
- Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø 3.3 mm implants.
- The healing time for diameter 3.3 mm implants is at least 12 weeks.

CONELOG® implants with 7 mm length have the following additional specific indications:

These Implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional.

Technological Characteristics

The CAMLOG® PROGRESSIVE-LINE / CONELOG® PROGRESSIVE-LINE Implants represent self-tapping implants with an outer geometry consisting of a coronal cylindrical portion and a conical apical portion. The CAMLOG® PROGRESSIVE-LINE Implants and the CONELOG® PROGRESSIVE-LINE Implants are available with the Promote® surface structure (Promote® / Promote® plus) which has a roughness R_a of typically 1.3 µm. The Promote® surface is achieved by abrasive sand blasting of machined titanium and subsequent acid etching. The shape and the surface structure (i.e. Promote® / Promote® plus) of the CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are substantially equivalent to that of the primary predicate device (K113779) and the reference predicate device (K083496).

The CONELOG® PROGRESSIVE-LINE implants feature the identical implant-abutment connection as CONELOG® SCREW-LINE implants (primary predicate device – K113779), allowing the use of exactly the same secondary parts for the prosthetic suprastructure. The implant abutment connection consists of the conical part and an index part with a groove/cam design (positioned apically). More apically, there is an inner thread for the abutment screw. The same thread is also used for the fixation of cover screws, healing abutments, bar and ball abutments, Locator® abutments, and insertion posts. The implant material and surface texture (Promote®) are identical to the predicate devices. The main difference is in the thread design in order to achieve good primary stability in bone.

The CAMLOG® PROGRESSIVE-LINE implants feature the identical Tube-in-Tube™ implant-abutment connection (i.e. inner configuration with three square grooves) as CAMLOG® SCREW-LINE or ROOT-LINE implants (reference predicate device – K083496), allowing the use of exactly the same secondary parts for the prosthetic suprastructure.

The CAMLOG® PROGRESSIVE-LINE and CONELOG® PROGRESSIVE-LINE Implants have a color code for the implant system for an easy identification of the prosthetic platform diameter.

The basic design principles of the CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are adapted from the CAMLOG®/CONELOG® SCREW-LINE & CAMLOG® ROOT-LINE implant systems (primary and reference predicate devices). For details on substantial equivalence, refer to Table 2 of this summary.

Although the wording in the Indications for Use is not identical between the subject devices and the predicate devices, the content is substantially equivalent for the subject devices and the primary predicate device (K113779). In both cases the subject and predicate devices are intended for surgical placement in the maxillary and/or mandibular bone for the purpose of attaching a dental prosthesis and include shared features (Refer to Table 2 of this summary) which demonstrate substantial equivalence in their respective designs. The totality of the preceding description and the mechanism of action as tested indicates that there is no substantial difference between the subject devices and the primary predicate device (K113779) with respect to either indications for use or technological characteristics. The proposed devices do not pose any new or increased risks as compared to the legally marketed predicate devices based on the performance evaluation conducted on the worst-case manufactured dimensions which supports the determination that the subject devices are appropriate for their intended use and do not render the devices not substantially equivalent.

Summary of Testing

Dynamic mechanical fatigue testing was performed on the CAMLOG® PROGRESSIVE-LINE and CONELOG® PROGRESSIVE-LINE utilizing the smallest implant body diameters (3.3 mm and 3.8 mm) and 13 mm implant lengths. The 13 mm-length implants were tested due to having sufficient length for proper fixation in compliance with ISO 14801, *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants*. The applicable abutment connection (i.e. CONELOG® or CAMLOG®), in a Universal abutment configuration or a Bar abutment (30° angled) configuration, was utilized with the CAMLOG® PROGRESSIVE-LINE implant or the CONELOG® PROGRESSIVE-LINE implant during the dynamic mechanical fatigue testing. The testing mechanical benchmarks (acceptance criterion) for fatigue testing of the CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants were based on the substantially equivalent predicate devices (CAMLOG® SCREW-LINE / ROOT-LINE Promote® & Promote® plus; CONELOG® SCREW-LINE Promote®) and they met the requirement regarding mechanical integrity demonstrating the strength of the PROGRESSIVE-LINE implants is appropriate for their intended use and is substantially equivalent to that of the predicate devices (K113779 & K083496).

Sterilization validation was performed on the gamma sterilization process. The sterilization validation was conducted on representative worst-case Altatec GmbH dental implant device (i.e. reference predicate device – K083496, CAMLOG® SCREW-LINE implant – Promote® plus). The requirements of ISO 11137-1, ISO 11137-2, and ISO 11137-3 were met with regard to the validation of the sterilization procedure of the product family CAMLOG®/CONELOG® SCREW-LINE and CAMLOG® ROOT-LINE. The sterilization validation testing demonstrates the compliance with the required minimum gamma radiation sterilization dose of 25 kGy and a maximum of 50 kGy (according to ISO 11137-3) for sterilization of CAMLOG®/CONELOG® Implants packaged by Altatec GmbH (the primary predicate device (K113779) and the reference predicate device (K083496) for the Progressive-Line Implants).

Tests for endotoxins are performed and non-endotoxin pyrogens evaluated according to the FDA Guidance on "Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile." The subject devices are submitted to a validated cleaning process within the manufacturing process. Manufacturing processes are analogous for all dental implants consisting of titanium grade 4 manufactured by Altatec GmbH. The cleaning process is identical for all of these implants including predicate devices (K113779

& K083496). The effectivity of the cleaning process for the implants is revalidated once per quarter of the year. To detect endotoxin levels on the finished implants, the Limulus Amebocyte Lysate (LAL) test is performed using the gel-clot technique, as per United States Pharmacopoeia (USP) 38-NF33, chapter 85, and the ANSI/AAMI ST72, within every revalidation. The endotoxin limit was derived from USP 38-NF33, chapter 161, "Transfusion and Infusion Assemblies and Similar Devices", that states, "For medical devices, the endotoxin limit is not more than 20.0 USP Endotoxin Units per device except that for those medical devices in contact with the cerebrospinal fluid ... "

Accelerated, artificial aging was accomplished for shelf life in accordance with ISO 11607-1, *Packaging for Terminally Sterilized Medical Devices - Part-1,* and ASTM F1980, *Standard Guide for Accelerated Aging of Sterile Barrier Systems for Medical Devices.* Shelf life has been established to be five years provided the sterile seal is not breached. The device is a titanium (CPTi Grade 4), non-mechanical, non-active device, therefore, degradation in performance characteristics will not occur over the established shelf life period. Special storage conditions are not required for the device, as ambient storage conditions will not adversely affect the safety or efficacy of the device.

The CAMLOG®/CONELOG® PROGRESSIVE-LINE Implants are made of the same implant grade material as the predicate devices (commercially pure titanium, CPTi Grade 4), meeting the requirements of ASTM F67-13. The abutment screws and abutments are made of a titanium alloy (Ti6Al4V ELI) which is listed in ASTM F136-13 and is the same material utilized by the predicate devices for the same items. The same manufacturing, cleaning, packaging, and sterilization processes are used for the evaluated devices, the primary predicate device (K113779) and the reference predicate device (K083496). A biological evaluation according to ISO 10993-1, *Biological Evaluation of Medical Devices – Part-1,* was completed for the PROGRESSIVE-LINE Implants. From the testing, the biological evaluation for the PROGRESSIVE-LINE implants indicated that the remaining risk regarding biocompatibility could be considered low and therefore acceptable. Test results concluded that the test articles were non-cytotoxic, non-irritating and negative for evidence of dermal sensitization under the test conditions employed and substantially equivalent to the predicate devices (K113779 & K083496).

Conclusion

The data presented in this submission demonstrates that the proposed devices are substantially equivalent to the primary predicate device with respect to performance and intended use. The proposed devices perform as well as the legally marketed predicate device. Furthermore, the proposed devices do not pose any new or increased risks as compared to the legally marketed predicate device.

Table 2: Summary Table of Substantial Equivalence

	Subject Device	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	EQUIVALENCE DISCUSSION
	CONELOG® PROGRESSIVE-LINE	CAMLOG® PROGRESSIVE-LINE	CONELOG® SCREW-LINE, Promote® K113779	CAMLOG® SCREW-LINE, Promote® & Promote® plus K083496	CAMLOG® ROOT-LINE, Promote® & Promote® plus K083496	
General						
Images						**Threaded Implant Body, All**
Clinical Condition When Used	partial or full edentulism	partial or full edentulism	partial or full edentulism	partial or full edentulism	partial or full edentulism	**Same for All**
Site of Body	both jaws (maxilla and/or mandible)	both jaws (maxilla and/or mandible)	both jaws (maxilla and/or mandible)	both jaws (maxilla and/or mandible)	both jaws (maxilla and/or mandible)	**Same for All**
Intended Use	functional and / or esthetical oral rehabilitation of partially or fully edentulous patients	functional and / or esthetical oral rehabilitation of partially or fully edentulous patients	functional and / or esthetical oral rehabilitation of partially or fully edentulous patients	functional and / or esthetical oral rehabilitation of partially or fully edentulous patients	functional and / or esthetical oral rehabilitation of partially or fully edentulous patients	**Same for All**
Indications	CONELOG® PROGRESSIVE-LINE implants are indicated for the restoration of edentulous and partially edentulous jaws with prosthetic restorations	CAMLOG® PROGRESSIVE-LINE implants are indicated for the restoration of edentulous and partially edentulous jaws with prosthetic	CONELOG® Implant System Implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. CONELOG®	CAMLOG® Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch. CAMLOG®	CAMLOG® Implant System implants are intended for immediate or delayed placement in the bone of the maxillary or mandibular arch.	**Substantially Equivalent** Although the wording in the Indications for Use are not identical between the subject devices and the predicate devices, the content is

Subject Device	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	EQUIVALENCE DISCUSSION
CONELOG® PROGRESSIVE-LINE	CAMLOG® PROGRESSIVE-LINE	CONELOG® SCREW-LINE, Promote® K113779	CAMLOG® SCREW-LINE, Promote® & Promote® plus K083496	CAMLOG® ROOT-LINE, Promote® & Promote® plus K083496	
such as implant-supported single crowns, bridges and full dentures. Specifically for: • single-tooth gaps, • partially edentulous jaws with several missing teeth or • edentulous jaws. CONELOG® PROGRESSIVE-LINE Implants are suitable for oral endosseous implantation in the maxillary and/or mandibular bone and are intended for immediate or delayed implantation. They are indicated for transgingival healing (one-stage, using healing caps or abutments) or subgingival healing (two-stage, using cover screws). If single-phase healing is intended, the implants can be loaded immediately if the primary stability achieved is adequate for functional loading. In conjunction with the corresponding abutments, the implants can be used for screw-retained or cemented restorations such as single crowns, bridges and full dentures.	restorations such as implant-supported single crowns, bridges and full dentures. Specifically for: • single-tooth gaps, • partially edentulous jaws with several missing teeth or • edentulous jaws. CAMLOG® PROGRESSIVE-LINE Implants are suitable for oral endosseous implantation in the maxillary and/or mandibular bone and are intended for immediate or delayed implantation. They are indicated for transgingival healing (one-stage, using healing caps or abutments) or subgingival healing (two-stage, using cover screws). If single-phase healing is intended, the implants can be loaded immediately if the primary stability achieved is adequate for functional loading. In conjunction with the corresponding abutments, the implants can be used for screw-retained or cemented restorations such as single crowns, bridges and full	Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate. CONELOG® Implants with 3.3 mm diameter have the following additional specific indications: These are an alternative in cases where the alveolar ridge width is only 5 - 6 mm. Because of their lower mechanical strength compared with larger diameter implants, they should only be used under the following conditions: • As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors. • An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal	Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.	CAMLOG® Implant System Abutments are intended for use as support for crowns, bridges or overdentures. When a one-stage surgical approach is applied, the implant may be immediately loaded when good primary stability is achieved and the functional load is appropriate.	substantially equivalent for the subject devices and the primary predicate device (K113779). The Indications for Use of the reference predicate devices (K083496) and the subject devices share the general indications that are corresponding with that of both the subject devices and the primary predicate device (K113779). In both cases the subject and predicate devices are intended for surgical placement in the maxillary and/or mandibular bone for the purpose of attaching a dental prosthesis. The totality of the preceding description and the mechanism of action as tested indicates that there is no substantial difference between the subject devices and the primary predicate device (K113779) with respect to either indications for use or technological characteristics. The proposed devices do not pose any new or increased risks as compared to the legally marketed predicate devices. Both the subject devices and predicate devices include shared features, as provided in this Summary Table of Substantial Equivalence, which thereby demonstrates substantial equivalence in their respective designs. Any specific differences related to implant shape, body diameter, external thread design and prosthetic

Subject Device	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	EQUIVALENCE DISCUSSION
CONELOG® PROGRESSIVE-LINE	CAMLOG® PROGRESSIVE-LINE	CONELOG® SCREW-LINE, Promote® K113779	CAMLOG® SCREW-LINE, Promote® & Promote® plus K083496	CAMLOG® ROOT-LINE, Promote® & Promote® plus K083496	
Implants with a diameter of 3.3 mm are indicated as an alternative in cases where the alveolar ridge width is only 5–6 mm. Because of their lower tensile strength compared with larger diameter implants, they should only be used under the following conditions: • As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors. • An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal extensions. • Implants of Ø 3.3 mm are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account. • Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø 3.3 mm implants.	dentures. Implants with a diameter of 3.3 mm are indicated as an alternative in cases where the alveolar ridge width is only 5–6 mm. Because of their lower tensile strength compared with larger diameter implants, they should only be used under the following conditions: • As single implants, they should be used only to replace mandibular incisors and/or maxillary lateral incisors. • An edentulous arch can only be restored with a bar retained superstructure with at least four implants of 3.3 mm diameter without distal extensions. • Implants of Ø 3.3 mm are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account. • Avoid excessive mechanical stressing of the implants when using ball abutments in	extensions. • Implants of Ø 3.3 mm are suitable for a partially edentulous arch when combined with implants of larger diameter for splinted superstructures. However, the limited strength of the implants with Ø 3.3 mm must be taken into account. • Avoid excessive mechanical stressing of the implants when using ball abutments in combination with Ø 3.3 mm implants. • The healing time for Ø 3.3 mm implants is at least 12 weeks. CONELOG® Implants with 7 mm length have the following additional specific indications: CONELOG® SCREW-LINE Implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the			platform connection geometry between the proposed devices and the predicate devices do not pose any new or increased risks as compared to the legally marketed predicate devices based on the performance evaluation conducted on the worst-case manufactured dimensions which supports the determination that the subject devices are appropriate for their intended use and do not render the devices not substantially equivalent.

	Subject Device	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	EQUIVALENCE DISCUSSION
	CONELOG® PROGRESSIVE-LINE	CAMLOG® PROGRESSIVE-LINE	CONELOG® SCREW-LINE, Promote® K113779	CAMLOG® SCREW-LINE, Promote® & Promote® plus K083496	CAMLOG® ROOT-LINE, Promote® & Promote® plus K083496	
	• The healing time for diameter 3.3 mm implants is at least 12 weeks. CONELOG® Implants with 7 mm length have the following additional specific indications: These Implants should only be used when there is not enough space for a longer implant. Delayed loading in single tooth replacement is indicated with these implants. If the ratio of crown length to implant length is unfavorable the biomechanical risk factors have to be considered and appropriate measures have to be taken by the dental professional.	combination with Ø 3.3 mm implants. • The healing time for diameter 3.3 mm implants is at least 12 weeks.	dental professional.			
Design						
Implant Shape	Dental implant with a cylindrical coronal section and a tapered apical section (same as CAMLOG® PROGRESSIVE-LINE)	Dental implant with a cylindrical coronal section and a tapered apical section	implant shape with a collar, a cylindrical coronal section and a tapered apical section (same as CAMLOG® SCREW-LINE)	implant shape with a collar, a cylindrical coronal section and a tapered apical section	implant shape with a collar, a short cylindrical coronal section and a longer tapered section if compared to SCREW-LINE	**CONELOG® PROGRESSIVE-LINE same as Primary & Reference Predicate; CAMLOG® PROGRESSIVE-LINE same as Primary & Reference Predicate (minus the collar)**
Implant Body Diameter	3.3, 3.8, 4.3, 5.0mm	3.3, 3.8, 4.3, 5.0mm	3.3, 3.8, 4.3, 5.0mm	3.3, 3.8, 4.3, 5.0, 6.0mm	3.8, 4.3, 5.0, 6.0mm	**Same as Primary Predicate; within body diameter range established by Reference Predicate**

	Subject Device	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	EQUIVALENCE DISCUSSION
	CONELOG® PROGRESSIVE-LINE	**CAMLOG® PROGRESSIVE-LINE**	**CONELOG® SCREW-LINE, Promote® K113779**	**CAMLOG® SCREW-LINE, Promote® & Promote® plus K083496**	**CAMLOG® ROOT-LINE, Promote® & Promote® plus K083496**	
Implant Length	7, 9, 11, 13, 16mm	9, 11, 13, 16mm	7, 9, 11, 13, 16mm	9, 11, 13, 16mm	9, 11, 13, 16mm	**CONELOG® PROGRESSIVE-LINE same as Primary Predicate; CAMLOG® PROGRESSIVE-LINE within implant length range established by Primary Predicate (minus the 7mm implant length) and same as Reference Predicate**
Outer thread	pitch 1.0mm	pitch 1.0mm	pitch 0.7mm	pitch 0.7mm	pitch 0.7mm	**Substantially Equivalent** The subject devices have a different thread pitch/design in order to achieve good primary stability in bone. The device related risks associated with the use of CAMLOG®/CONELOG® PROGRESSIVE-LINE were assessed and determined to be substantially equivalent to the predicate devices (i.e. FMEA). Dynamic mechanical fatigue testing results indicate performance is suitable for the intended use and are substantially equivalent to the predicate devices.
Surface	Promote® surface	Promote® surface	Promote® surface	Promote® surface	Promote® surface	**Same for All (i.e. Promote® / Promote® plus)**
Implant Abutment Connection	CONELOG® conical connection with a distal section having 3 cams to control rotational position	CAMLOG® tube-in-tube connection, indexing section having 3 cams to control rotational position	CONELOG® conical connection with a distal section having 3 cams to control rotational position	CAMLOG® tube-in-tube connection, indexing section having 3 cams to control rotational position	CAMLOG® tube-in-tube connection, indexing section having 3 cams to control rotational position	**CONELOG® PROGRESSIVE-LINE same as Primary Predicate; CAMLOG® PROGRESSIVE-LINE same as Reference Predicate**
Implant Neck	no machined neck, undercut in neck area	0.4mm machined, undercut in neck area	no machined neck, undercut in neck area	either 1.4 or 0.4mm machined, undercut in neck area	either 2.0 or 0.4mm machined, undercut in neck area	**CONELOG® PROGRESSIVE-LINE same as Primary Predicate; CAMLOG® PROGRESSIVE-LINE same as Reference Predicate**

	Subject Device	Subject Device	Primary Predicate Device	Reference Predicate Device	Reference Predicate Device	EQUIVALENCE DISCUSSION
	CONELOG® PROGRESSIVE-LINE	CAMLOG® PROGRESSIVE-LINE	CONELOG® SCREW-LINE, Promote® K113779	CAMLOG® SCREW-LINE, Promote® & Promote® plus K083496	CAMLOG® ROOT-LINE, Promote® & Promote® plus K083496	
Material and Manufacturing						
Implant Material	CPTi	CPTi	CPTi	CPTi	CPTi	**Same for All**
Manufacturing process	Machined by Altatec GmbH	Machined by Altatec GmbH	Machined by Altatec GmbH	Machined by Altatec GmbH	Machined by Altatec GmbH	**Same for All**
Packaging	sterile packed (implants & cover screws)	sterile packed (implants & cover screws)	sterile packed (implants & cover screws)	sterile packed (implants & cover screws)	sterile packed (implants & cover screws)	**Same for All**
Sterilization	gamma sterilization	gamma sterilization	gamma sterilization	gamma sterilization	gamma sterilization	**Same for All**