February 2, 2020

Argon Med. Productions Vertriebs Gesellschaft MBH Co Kg
℅ Celline Lakus
Business Manager
Argon Dental USA, LLC
1000 Corporate Drive
Marshfield, Wisconsin 54449

Re: K190192
Trade/Device Name: K3Pro® Konus New Abutments and Implants
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 14, 2020
Received: January 14, 2020

Dear Celline Lakus:

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)*
K190192

Device Name
K3Pro® Konus New Abutments and Implants

Indications for Use *(Describe)*
The K3Pro® Konus New Abutments and Implants are designed to be compatible with the K3Pro® Konus Dental Implant system and are for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement. Delayed loading is recommended.

The Ø7, 8, and 9mm implants are intended only for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications.

All digitally designed abutments for use with K3Pro® New Abutments and Implants are intended to be sent to an Argon 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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K190192

510(k) Summary

Date Submitted	February 1, 2019	**Revision Date**	February 10, 2020
Manufacturer and Address	Argon Medical Productions & Vertriebs Gesellschaft mbH & Co. KG Franz-Kirsten-Str. 1 Bingen am Rhein, Germany, 55411		
Manufacturer Contact	Richard Donaca CEO/Managing Director Tel: 011-49-6721-3096-0 Fax: 011-49-6721-3096-29		
US Agent	Argon Dental USA, LLC 1000 Corporate Dr. Marshfield, WI. 54449		
US Agent Contact	Celline Lakus Business Manager Tel:715-898-1434 Fax:715-387-4100		
Proposed Trade Name	K3Pro® Konus New Abutments and Implants		
Common Name	Endosseous Dental Implants		
Device Class	Class II		
Regulation	21 CFR 872.3640		
Device Product Codes	DZE: Primary NHA: Secondary		
Purpose	The purpose of this submission is to expand the Argon Medical K3Pro® Konus Dental Implant System components cleared under K141159 and K160581. As such, this submission includes new implant bodies and additional abutments for previously cleared K3Pro® Implants (K141159 and K160581).		

Device Description and Intended Use

- The connection portion and the subject devices are manufactured by Argon Medical Productions & Vertriebs Gesellschaft mbH & Co. KG of Germany, the additional devices are part of the previously FDA cleared K3Pro® Konus Dental Implant System K141159 and K3Pro® Additional Abutments and Implants K160581.

- The Abutments in this submission are in two prosthetic platform diameters (2.0mm & 3.0mm). The abutments are designed to fit and function only on the previously cleared K3Pro® Konus Dental Implants (K141159), the additional implants submitted in K3Pro® Additional Abutments and Implants (K160581) and the implants submitted in this submission. They have the same Konus connection and are screw retained.

- Abutment screws: They are made of the same Titanium as the implants (pure, grade 4 titanium), to fix abutments to the underlining dental implant.

- All K3Pro® abutments and implant bodies are not reusable, and they are for single use only.

- **The K3Pro® Implants** in this submission are 7.0mm and 8.0mm in diameter. They are provided in 3.0mm platform only and range in length from 8.0 to 11.0mm (8.0, 9.0 and 11.0mm). They are manufactured from pure Grade 4 titanium. The implant surface has been treated with Osteo-Active™ (cleared in K141159) and is identical to all other K3Pro® Implants cleared on submissions K141159 and K160581. They have a self-tapping thread design, cutting groove and conical implant body which allows for a directed implant placement. The K3Pro® Implant System connects the implant and abutment with a 1.5° taper per side (total 3° taper). The implant has sloping shoulder and is intended to be 1mm subcrestally inserted and for delayed loading.

- Implants in this submission are available in the following diameters and lengths:

Picture	Implant Diameter	Platform Diameter	Implant Lengths	Implant Material
	7.0mm	3mm	8.0, 9.0 and 11.0mm	Grade 4 Ti with Osteo-Active™ surface treatment
	8.0mm	3mm	8.0, 9.0 and 11.0mm	Grade 4 Ti with Osteo-Active™ surface treatment

- **The K3Pro® Implants** in this submission are compatible with ALL 3.0mm platform abutments in this submission as well as 3.0mm platform abutments cleared in K141159 and K160581 (Sure, Rapid and Short).
- **The K3Pro® Ti-Base Abutments** in this submission – KSA, CG.C, CG.V and CS abutments – are provided in two platform diameters (2.0mm & 3.0mm). Angled abutments and the 2mm connection implants are to be used in splint or multi- unit restorations only and not in single tooth restorations. These are only recommended for the incisor region of the mouth. Ø4.0 diameter implants and angled abutments (CG.C, CG.V, KSA) are only recommended for use in the anterior of the mouth. Ø4.0 diameter implants and CS angled abutments are only recommended for use in the incisor region of the mouth. The subject abutments are made of titanium alloy (Grade 5 Ti-6Al 4V-ELI), conforming to ASTM F136 Standard Specification for Wrought Titanium- 6Aluminum4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications (UNS R56401), same material as the K3Pro® abutments previously cleared in K141159 and K160581. The screws are made from Grade 4 Titanium, the same material as the implants. The subject abutments are only compatible with K3Pro® Konus Dental Implants cleared in K141159 and K160581, and the implant bodies in this submission.

Device Description and Intended Use (continued)

- The Ti-Base Abutments in this submission are available in the following diameters and lengths:

Ti-Base Abutment Type	Platform Diameter (mm)	Abutment Diameter (mm)	Abutment Gingival Height (mm)	Abutment Angulation	Abutment Material	Implant to Abutment Compatibility
KSA (Subject Device) 	2mm	4.0mm	0.5, 1.5 and 2.5mm	0, 10 and 20°	Grade 5 Ti-6Al 4V-ELI	3.0 and 3.5mm Sure and Rapid (cleared in K141159)
	3mm	5.0mm	0.5, 1.5 and 2.5mm	0, 10 and 20°	Grade 5 Ti-6Al 4V-ELI	4.0, 4.5, 5.0, 6.0mm Sure, Rapid and Short (cleared in K141159 and K160581) **7.0 and 8.0mm (Subject Devices)**
CG.C (Subject Device) 	2mm	F1 (Front) P2 (Incisor)	1.5mm	0°	Grade 5 Ti-6Al 4V-ELI	3.0 and 3.5mm Sure and Rapid (K141159)
	3mm	P2 (Incisor) M1 (Molar)	0.5 and 1.5mm	0°	Grade 5 Ti-6Al 4V-ELI	4.0, 4.5, 5.0, 6.0mm Sure, Rapid and Short (cleared in K141159 and K160581) **7.0 and 8.0mm (Subject Devices)**
CG.V (Subject Device) 	2mm	4.0mm	0.5 and 1.5mm	0°	Grade 5 Ti-6Al 4V-ELI	3.0 and 3.5mm Sure and Rapid (cleared in K141159)
	3mm	4.0mm	0.5 and 1.5mm	0°	Grade 5 Ti-6Al 4V-ELI	4.0, 4.5, 5.0, 6.0mm Sure, Rapid and Short (cleared in K141159 and K160581) **7.0 and 8.0mm (Subject Devices)**
CS (Subject Device) 	2mm	4.0mm	0.5 and 1.5mm	0°	Grade 5 Ti-6Al 4V-ELI	3.0 and 3.5mm Sure and Rapid (cleared in K141159)
	3mm	4.0 and 4.5mm	0.5 and 1.5mm	0°	Grade 5 Ti-6Al 4V-ELI	4.0, 4.5, 5.0, 6.0mm Sure, Rapid and Short (cleared in K141159 and K160581) **7.0 and 8.0mm (Subject Devices)**

- This submission includes Titanium-base type abutments to be used as the apical part of two-piece abutments. They are manufactured by Argon Medical Productions of Germany and are for use with only the K3Pro® Implants. They are made of titanium alloy, have a prefabricated, precision interface (implant/abutment connection) and are to be used for fabrication of patient-specific abutments using FDA cleared CAD/CAM technology such as 3Shape Abutment Design Software (K151455). Each patient-specific abutment is individually prescribed by the clinician and manufactured by an Argon Medical Productions validated milling center.

- The Zirconium coping and/or crown of the K3Pro® Ti-Base type abutments are to be made of biocompatible ZrO2 conforming to *ISO 13356:2015 - Implants for surgery – Ceramic materials based on yttria-stabilized tetragonal zirconia (Y-TZP*) and luted to the abutment with an FDA cleared cement (MultiLink Hybrid Cement - K130436 is the product used in the ISO 14801 testing for this submission).

Device Description and Intended Use (continued)

- The zirconia superstructure/coping and abutment bodies, follows the minimum and maximum tolerances:

NOTE 1: The total angulation of abutment base and zirconia coping should not exceed the angulation listed above.

Zirconia Coping/Abutment Tolerances				
	CG.C	**CG.V**	**KSA**	**CS**
Minimum Wall Thickness	0.5mm	0.5mm	0.5mm	0.5mm
Minimum Emergence Diameter	3.3mm	3.3mm	3.3mm	3.3mm
Maximum Angulation	30°	0°	20°	0°
Minimum Cementable Height from Emergence Profile	4mm	4mm	4mm	4mm
Maximum Cementable Height from Emergence Profile	14.2mm	14.2mm	14.2mm	14.2mm

NOTE 2: 30° Abutments and the 2 mm connection implants are to be used in splint or multi-unit restorations only and not in single tooth restorations. These are not recommended for use in the posterior region of the mouth.

Indications for Use

The K3Pro® Konus New Abutments and Implants are designed to be compatible with the K3Pro® Konus Dental Implant system and are for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement. Delayed loading is recommended.

The Ø7, 8, and 9mm implants are intended only for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications.

All digitally designed abutments for use with K3Pro® New Abutments and Implants are intended to be sent to an Argon validated milling center for manufacture.

Predicate Devices

PRIMARY:

1. **K3Pro® Konus Additional Abutments and Implants *(K160581)***

REFERENCE:

2. **NSI Endosseous Dental Implant System *(K071161)***
   - Reference for 7.0 and 8.0 diameter implants
3. **Certain BellaTek® Express and BellaTek® Flex Abutments *(K183138)***
   - Reference for Ti-Base Hybrid abutments

Comparison of INDICATIONS FOR USE

System:	K3Pro® Konus New Abutments and Implants	K3Pro® KonusAdditional Abutments and Implants (Primary Predicate)	NSI Endosseous Dental Implants (Reference Device for proposed implants)	Certain BellaTek® Express and BellaTek® Flex Abutments (Reference Device for proposed Ti-Base Hybrid abutments)	Similarities and Differences
510(k) number	Subject Device	K160581 Primary Predicate	K071161 Reference Device	K183138 Reference Device	N/A
Indications for Use	The K3Pro® Konus New Abutments and Implants are designed to be compatible with the K3Pro® Konus Dental Implant system and are for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement. Delayed loading is recommended. The Ø7, 8, and 9mm implants are intended only for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. All digitally designed abutments for use with K3Pro® New Abutments and Implants are intended to be sent to an Argon validated milling center for manufacture.	K3Pro® Konus Additional Abutments and Implants are designed to be compatible with the K3Pro® Konus Dental Implant system and are for use in edentulous sites in the mandible or maxilla for support of a complete denture prosthesis, a final or intermediate abutment for fixed bridgework or for partial dentures, or as a single tooth replacement. Delayed loading is recommended. The prosthesis may be secured to the abutment by the use of adhesives or mechanically by the use of a screw.	The NSI MAX Implant System is intended for implantation in the maxillary or mandibular molar region where bone exists and the surgeon has determined that the placement of a narrower diameter implant would increase the probability of failure due to poor primary stability, or increased surgical procedures leading to complications. This MAX implant provides support for fixed or removable dental prostheses in a single tooth, partially edentulous prostheses, or full arch prostheses. It further adds the option for immediate loading on single and splinted multiple unit restorations when good primary stability is achieved and with appropriate occlusal loading, to restore chewing functions.	Certain BellaTek Express and BellaTek Flex Abutments are intended for use as accessories to endosseous dental implant to support a prosthetic device in a partially or completely edentulous patient. A dental abutment is intended for use to support single and multiple tooth prosthesis, in the mandible or maxilla. The prosthesis can be screw retained or cement retained. All digitally designed superstructure and/or hybrid abutment crowns for use with Certain BellaTek Express and BellaTek Flex Abutments are intended to be sent to a Biomet 3i validated milling center for manufacture.	The subject Indications for Use first paragraph is similar to the primary predicate Indications for Use. Language specific to validated milling center has been added, identical to the reference device used for this technology (K183138). Additionally, language specific to the placement of large diameter implant bodies has been added, identical to the reference device used for this technology (K071161)

Comparison of TECHNOLOGICAL CHARACTERISTICS – Subject Device – Implants

System:	K3Pro® Konus New Abutments and Implants	K3Pro® KonusAdditional Abutments and Implants (Primary Predicate)	NSI Endosseous Dental Implants	Similarities and Differences
510(k) number	Subject Device	K160581 Primary Predicate	K071161 Reference Device	N/A
Material of Manufacture	Grade 4 Ti (commercially pure titanium)	Grade 4 Ti (commercially pure titanium)	Grade 4 Ti (commercially pure titanium)	Same as implants in Primary and Reference Devices (K160581 and K071161)
Implant Surface	OsteoActive® Surface	OsteoActive® Surface	SInergy™ Surface	Same as Primary Predicate K160581
Implant Body Diameter	7.0, 8.0mm	4.0, 4.5, 5.0, 6.0mm	8.0, 9.0mm	Different from Primary Predicate (K160581) Within Reference Device available diameters (K071161). Subject device proposes a smaller diameter than the Reference Device, which does not impact substantial equivalence.
Implant Body Length	8.0, 9.0, 11.0mm	5.5, 6.5, 7.5, 8.0, 9.0mm	7.0, 9.0, 11.0, 13.0mm	8.0 and 9.0mm lengths are within range of Primary Predicate (K160581) and 9.0 and 11.0mm length are within range of Reference Device (K071161)
Implant Platform	3mm	3mm	Not publicly available	Same as Primary Predicate K160581
Implant Connection to Abutment	Internal Hex alignment, 1.5° locking conical taper, screw attachment or cement	Internal Hex alignment, 1.5° locking conical taper, screw attachment or cement	Internal Tri-lobe hex connection (TRI-NEX®), screw attachment or cement	Same as Primary Predicate K160581

Comparison of TECHNOLOGICAL CHARACTERISTICS – Subject Device – Ti-Base Abutments – CG.C

System:	K3Pro® Konus New Abutments and Implants	K3Pro® KonusAdditional Abutments and Implants - K3Pro® CAD Blanks and UNI.CAD Blanks (Primary Predicate)	Certain BellaTek® Express and BellaTek® Flex Abutments (Reference Device)	Similarities and Differences
510(k) number	Subject Device	K160581 Primary Predicate	K183138 Reference Device	N/A
Material of Manufacture	Grade 5 Ti-6Al 4V-ELI and Zirconia	Grade 5 Ti-6Al 4V- ELI	Grade 5 Ti-6Al 4V-ELI and Zirconia	Similar to Primary Predicate (K160581) with the addition of the zirconia and Same as Reference Device (K183138)
Abutment Type	Two-Piece/Ti-Base	Blank-Type	Two-Piece/Ti-Base	Different from Primary Predicate (K160581). Same as Reference Device (K183138)
Abutment Diameter	4.0mm	10.0mm and 16.0mm	3.4, 4.1, 5.0 and 6.0mm	Different from Primary Predicate (K160581). Within range of Reference Device (K183138)
Abutment Post Height	4.0 – 14.2mm	4.0 – 14.2mm	4.7 – 12.0mm	Same as Primary Predicate K160581
Connection to Abutment	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Biomet 3i Internal Hex Implants, screw or cement retained	Same as Primary Predicate K160581
Implant/Abutment Connection	K3Pro® Implants 2.0 and 3.0mm internal connection	K3Pro® Implants 2.0 and 3.0mm internal connection	Biomet 3i Internal Hex Implants	Same as Primary Predicate K160581
Range of Abutment Gingival Height	0.5 – 1.5mm	0.5 – 2.5mm	0.25 – 6mm	Within range of Primary Predicate K160581
Range of Abutment Angulation	0^o - Zirconia coping can be angled up to 30^o	0 - 30^o	0^o	Within range of Primary Predicate K160581

Comparison of TECHNOLOGICAL CHARACTERISTICS – Subject Device – Ti-Base Abutments – CG.V

System:	K3Pro® Konus New Abutments and Implants	K3Pro® Konus Additional Abutments and Implants - K3Pro® CAD Blanks and UNI.CAD Blanks (Primary Predicate)	Certain BellaTek® Express and BellaTek® Flex Abutments (Reference Device)	Similarities and Differences
510(k) number	Subject Device	K160581 Primary Predicate	K183138 Reference Device	N/A
Material of Manufacture	Grade 5 Ti-6Al 4V-ELI and Zirconia	Grade 5 Ti-6Al 4V- ELI	Grade 5 Ti-6Al 4V-ELI and Zirconia	Similar to Primary Predicate (160581) with the addition of the zirconia and Same as Reference Device (K183138)
Abutment Type	Two-Piece/Ti-Base	Blank-Type	Two-Piece/Ti-Base	Different from Primary Predicate (K160581). Same as Reference Device (K183138)
Abutment Diameter	4.0mm	10.0mm and 16.0mm	3.4, 4.1, 5.0 and 6.0mm	Different from Primary Predicate (K160581). Within range of Reference Device (K183138)
Abutment Post Height	4.0 – 14.2mm	4.0 – 14.2mm	4.7 – 12.0mm	Same as Primary Predicate K160581
Connection to Abutment	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Biomet 3i Internal Hex Implants, screw or cement retained	Same as Primary Predicate K160581
Implant/Abutment Connection	K3Pro® Implants 2.0 and 3.0mm internal connection	K3Pro® Implants 2.0 and 3.0mm internal connection	Biomet 3i Internal Hex Implants	Same as Primary Predicate K160581
Range of Abutment Gingival Height	0.5 – 1.5mm	0.5 – 2.5mm	0.25 – 6mm	Within range of Primary Predicate K160581
Range of Abutment Angulation	0^o	0 - 30^o	0^o	Same as Reference Device (K183138)

Comparison of TECHNOLOGICAL CHARACTERISTICS – Subject Device – Ti-Base Abutments – KSA

System:	K3Pro® Konus New Abutments and Implants	K3Pro® Konus Additional Abutments and Implants - K3Pro® CAD Blanks and UNI.CAD Blanks (Primary Predicate)	Certain BellaTek® Express and BellaTek® Flex Abutments (Reference Device)	Similarities and Differences
510(k) number	Subject Device	K160581 Primary Predicate	K183138 Reference Device	N/A
Material of Manufacture	Grade 5 Ti-6Al 4V-ELI and Zirconia	Grade 5 Ti-6Al 4V- ELI	Grade 5 Ti-6Al 4V-ELI and Zirconia	Similar to Primary Predicate (160581) with the addition of the zirconia and Same as Reference Device (K183138)
Abutment Type	Two-Piece/Ti-Base	Blank-Type	Two-Piece/Ti-Base	Different from Primary Predicate (K160581). Same as Reference Device (K183138)
Abutment Diameter	4.0mm and 5.0mm	10.0mm and 16.0mm	3.4, 4.1, 5.0 and 6.0mm	Different from Primary Predicate (K160581). Within range of Reference Device (K183138)
Abutment Post Height	4.0 – 14.2mm	4.0 – 14.2mm	4.7 – 12.0mm	Same as Primary Predicate K160581
Connection to Abutment	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Biomet 3i Internal Hex Implants, screw or cement retained	Same as Primary Predicate K160581
Implant/Abutment Connection	K3Pro® Implants 2.0 and 3.0mm internal connection	K3Pro® Implants 2.0 and 3.0mm internal connection	Biomet 3i Internal Hex Implants	Same as Primary Predicate K160581
Range of Abutment Gingival Height	0.5 – 2.5mm	0.5 – 2.5mm	0.25 – 6mm	Same as Primary Predicate K160581
Range of Abutment Angulation	0 – 20°	0 - 30°	0°	Within range of Primary Predicate K160581

Comparison of TECHNOLOGICAL CHARACTERISTICS – Subject Device – Ti-Base Abutments – CS

System:	K3Pro® Konus New Abutments and Implants	K3Pro® Konus Additional Abutments and Implants - K3Pro® CAD Blanks and UNI.CAD Blanks (Primary Predicate)	Certain BellaTek® Express and BellaTek® Flex Abutments (Reference Device)	Similarities and Differences
510(k) number	Subject Device	K160581 Primary Predicate	K183138 Reference Device	N/A
Material of Manufacture	Grade 5 Ti-6Al 4V-ELI and Zirconia	Grade 5 Ti-6Al 4V- ELI	Grade 5 Ti-6Al 4V-ELI and Zirconia	Similar to Primary Predicate (160581) with the addition of the zirconia and Same as Reference Device (K183138)
Abutment Type	Two-Piece/Ti-Base	Blank-Type	Two-Piece/Ti-Base	Different from Primary Predicate (K160581). Same as Reference Device (K183138)
Abutment Diameter	4.0mm and 4.5mm	10.0mm and 16.0mm	3.4, 4.1, 5.0 and 6.0mm	Different from Primary Predicate (K160581). Within range of Reference Device (K183138)
Abutment Post Height	4.0 – 14.2mm	4.0 – 14.2mm	4.7 – 12.0mm	Same as Primary Predicate K160581
Connection to Abutment	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Hex alignment, 1.5° locking conical taper, screw attachment or cement	Biomet 3i Internal Hex Implants, screw or cement retained	Same as Primary Predicate K160581
Implant/Abutment Connection	K3Pro® Implants 2.0 and 3.0mm internal connection	K3Pro® Implants 2.0 and 3.0mm internal connection	Biomet 3i Internal Hex Implants	Same as Primary Predicate K160581
Range of Abutment Gingival Height	0.5 – 1.5mm	0.5 – 2.5mm	0.25 – 6mm	Within range of Primary Predicate K160581
Range of Abutment Angulation	0^o	0 - 30^o	0^o	Within range of Primary Predicate K160581

Summary of Technological Characteristics: The physical properties and designs of the K3Pro® Konus New Abutments and Implants were compared to legally marketed predicate devices. The technological characteristics were comparable.

The abutments are Titanium-base type abutments to be used as the apical part of two-piece abutment same as reference device Certain BellaTek® Express and BellaTek® Flex Abutments (K183138). They are available in both 2 and 3mm platform diameters (same as Primary Predicate K160581). The subject abutments are designed to only mate with the implants submitted in the K3Pro® Konus implants (K141159) and K3Pro® Konus Additional Abutments and Implants (K160581) previously cleared and legally marketed, and the implants bodies in this submission (same as the abutments included in the Primary Predicate submission (K160185).

The subject device and the predicate devices have similar instructions for use, connection and surface treatment, incorporate the same materials and design, are packaged and sterilized using the same materials and processes.

Substantial Equivalence Discussion: The comparison above outline the similarities between the predicate and proposed devices. Argon has presented comparative data in the preceding paragraphs that demonstrate that the K3Pro® New Abutments and Implants are substantially equivalent to the predicate devices. Any differences between the proposed device and the predicate device do not impact substantial equivalence.

Non-Clinical Testing: Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include:

- *Gamma sterilization validation* according to ISO 11137-3 (conducted on the proposed implants);
- *Steam sterilization validation* according to ISO 17665-1:2006 and ISO 11138-3:2006 T79] (referenced from K141159 for proposed implants and conducted on the proposed abutments);
- *Drying time validation* according to ANSI/AAMI ST79:2010 & A1:2010 (conducted on proposed abutments);
- *Pyrogenicity* information according to FDA Guidance, "Submission and Review of Sterility Information in Premarket Notification (510 (k)) Submissions for Devices Labeled as Sterile: LAL endotoxin test according to USP [85] (conducted on the proposed implants);
- *Biocompatibility* assessment according to ISO 10993-1 and cytotoxicity testing according to ISO 10993-5] (conducted on the proposed implants and abutments);
- *Fatigue testing* according to ISO 14801 and FDA Special Controls Guidance Document Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments (conducted on proposed abutments).
- *Shelf Life of Implant Bodies*: The implant bodies in this submission have the identical packaging to the implants cleared under primary predicate K160581. Additionally, the subject implants are currently under *Real Time Age testing for Validation of Claimed Shelf Life* according to ASTM F 1886. The current results have been provided for review.

No animal testing or human clinical trials have been conducted.

Surface area analysis of the submission device was previously established in the review of K141159.

Conclusion: The subject device and the predicate devices have the same indication for use, similar technological characteristics, and are made of similar if not identical materials; the non-clinical performance test data also supports equivalence to the predicates listed. The subject and predicate devices encompass similar physical dimensions, including diameter, length and surface area of the implants. The subject and predicate devices are packaged in comparable materials. The implants are provided sterile, and the abutments are sterilized by the end user with equivalent methods. The data provided in this submission supports the finding of the K3Pro® New Abutments and Implants to be substantially equivalent to the predicate devices referenced above.