July 21, 2022

B.T.I. Biotechnology Institute, SL
Jose Rivero
Qualified Person
Leonardo Da Vinci 14, Parque Tecnologico de Alava
Minano, Alava 01510
SPAIN

Re: K211952
Trade/Device Name: BTI Interna Narrow/Plus Dental Implant System UnicCa®
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: June 10, 2021
Received: June 21, 2021

Dear Jose Rivero:

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,

Andrew I. Steen
Assistant Director
DHT1B: Division of Dental and ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211952

Device Name
BTI Interna Narrow/Plus Dental Implant System UnicCa®

Indications for Use *(Describe)*
The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function.

In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations.

In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

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 – K211952

1. APPLICANT INFORMATION

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Contact Person: Mr. José Ramón Rivero
Date prepared: 7/21/2022

2. DEVICE NAME AND CLASSIFICATION

Name of Device: BTI Interna Narrow/Plus Dental Implant System UnicCa®
Primary Product Code: DZE
Secondary Product Code: NHA
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous dental implant, Endosseous dental implant abutment.
Regulatory Class: II

3. PREDICATE DEVICES

The primary predicate device is the BTI Dental Implant System UnicCa® Interna®, which was subject of K151391 (cleared on May 2, 2016). In addition, the following predicates/reference devices have been identified for respective implants and prosthetic components described within this premarket notification:

- B.T.I. Biotechnology Institute, S.L. Dental Implant System, cleared under K022258,
- BTI Interna Dental Implant System, cleared under K053355,
- BTI Sterile Dental Drills Kit, BTI Abutments and Caps, cleared under K061383,
- BIOMET 3i ™, cleared under K133049,
- S.I.N. Dental Implant System, cleared under K170392,
- Straumann Healing Abutments, Healing Caps, and Closure Screws, cleared under K130808.
- Straumann® Variobase™ Abutments, cleared under K132219,
- Straumann® Magellan Abutment System, cleared under K133421,
- On1 Concept, cleared under K161655,
- Straumann® CARES® Golden Ti/TiN Abutments, cleared under K162848,
- Straumann® Screw Retained Abutments, cleared under K171757, and
- Straumann® Variobase™ for Bridge/Bar Cylindrical, cleared under K173968.
- DESS Dental Smart Solutions, cleared under K170588.

4. DEVICE DESCRIPTION

BTI Dental Implant System UnicCa® is a self-tapping, threaded, root form dental titanium implant provided in two types of connections: external (i.e., Externa®) and internal (i.e., Interna®), in a variety of platforms and range of diameters (3.0 – 6.0 mm) and lengths (5.5 – 18.0 mm). BTI Dental Implant System UnicCa® features an implant surface treatment that improves the hydrophilicity of the implant.

The purpose of this 510(k) is to expand the product offering and include a new dental implant platform (Interna Narrow), and compatible abutments, together with additional implants for the already existing Universal Plus platform. Interna Narrow implants will be offered with implant diameters ranging from 3.3 to 4.75 mm and lengths of 5.5 to 15 mm. Additionally, new implants for the existing Universal Plus platform of diameter 6.0 mm, and lengths of 7.5 to 11.5 mm are included. The dental implants subject of this submission are summarized in the table below:

Connection	Platform	Platform diameter (mm)	Diameter (mm)	Length (mm)
Interna	Narrow	3.5	3.3	6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
			3.5	6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
			3.75	6.5 / 7.5 / 8.5 / 10 / 11.5 / 13 / 15
			4.0	5.5 / 6.5 / 7.5 / 8.5 / 10 / 11.5 / 13
			4.25	5.5 / 6.5 / 7.5 / 8.5 / 10 / 11.5 / 13
			4.75	5.5 / 6.5 / 7.5 / 8.5 / 10 / 11.5
	Universal Plus	4.1	6.0	7.5 / 8.5 / 10 / 11.5

The Compatible abutments in this submission are to be used with the Interna Narrow implants, and encompasses Healing abutments, Healing Screws, Temporary titanium abutments, Titanium abutments, Transepithelial abutments, Healing Caps, Interfaces and Screws.

The BTI Interna Narrow/Plus Dental Implant System UnicCa® has identical indications for use, operating principle, incorporates identical or similar materials, has identical implant surface treatment, and possesses the same shelf-life, packaging and sterilization processes than the identified predicate devices.

5. INDICATIONS FOR USE

The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function.

In the case of 5.5 – 6.5mm long UnicCa® implants: These implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations.

In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability and an appropriate occlusal load.

6. TECHNOLOGICAL CHARACTERISTICS

The proposed UnicCa® Interna Narrow/Plus Dental Implant System UnicCa® has the following similarities to those which previously received 510(k) concurrence via K053355, K061383 and K151391:

- has identical indications for use,
- uses identical operating principle,
- incorporates identical or similar materials,
- has identical implant surface implant treatment and
- is packaged and sterilized using identical materials and processes.

To bridge the gap in dimensional changes and surface coatings, additional devices of other commercially available dental implant lines, intended for similar use as the subject device are identified; specifically, the following ones:

- BIOMET 3i ™, cleared under K133049,
- S.I.N. Dental Implant System, cleared under K170392,
- Straumann Healing Abutments, Healing Caps, and Closure Screws, cleared under K130808.
- Straumann® Variobase™ Abutments, cleared under K132219,
- Straumann Magellan™ Abutment System, cleared under K133421,
- On1 Concept, cleared under K161655,
- Straumann® CARES® Golden Ti/TiN Abutments, cleared under K162848,
- Straumann® Screw Retained Abutments, cleared under K171757 and
- Straumann® Variobase™ for Bridge/Bar Cylindrical, cleared under K173968.
- DESS Dental Smart Solutions, cleared under K170588.

A comparison of the device features, indications for use, bench testing and other information shows that the proposed BTI Interna Narrow/Plus Dental Implant System UnicCa® is substantially equivalent to the predicate devices. **Table 5-3** compares the subject device to selected predicate devices.

The subject dental implants are substantially equivalent to those BTI dental implants currently cleared under K151391. Additional devices BIOMET 3i™ and S.I.N. Dental Implant System are identified for support of those implants whose dimensional combination are not covered by those BTI implants already cleared.

The subject Closure Screws are substantially equivalent to those cleared in BTI 510(k) K022258. Additional predicate, Straumann Healing Abutments, cleared under K130808, is identified for support of substantial equivalence of abutment gingival height. The Closure Screws packaging is identical to that in K151391.

The subject Healing abutments are substantially equivalent to those cleared in BTI 510(k) K061383. Additional BTI predicate K022258 is included for support of substantial equivalence of abutment Ø3.5

mm. The Straumann Healing Abutments, cleared under K130808 are identified for support of the reduced design of the subject Healing abutments.

The subject Temporary Titanium Abutments are substantially equivalent to the corresponding BTI Temporary Abutments cleared under K053355. Additional BTI Temporary abutments cleared under K022258 are identified as it included similar Temporary Titanium abutments of Ø3.5 mm and for support of those used with Transepithelial abutments.

The subject Titanium Abutments (Titanium Bioabutments and Square Aesthetic Abutments) are substantially equivalent to the corresponding design cleared for BTI Titanium abutments in K053355. Straumann® Variobase™ Abutments, cleared under K132219, Straumann® Variobase™ for Bridge/Bar Cylindrical, cleared under K173968, and Straumann® CARES Golden Ti/TiN Abutments, cleared under K162848, are identified because they included similar abutment heights and surface treatment (Titanium Nitride, TiN) as the proposed device.

The subject Transepithelial Abutments (Unit, Multi-im) are substantially equivalent to those design of BTI Transepithelial abutments already cleared under K061383, and those Titanium Abutments engaging design with dental implant cleared under K053355. Straumann® Screw Retained Abutments, cleared under K171757, is identified for support of the Ø3.5 mm, and Straumann® CARES® Golden Ti/TiN Abutments, cleared under K162848, for support of the coating material (Titanium Nitride, TiN). DESS Dental Smart Solutions is identified because it included a similar DLC coating applied to the retention screw thread in subject device.

The subject Healing caps are substantially equivalent to those BTI protection caps design cleared under K022258. On1 Concept, cleared under K161655, is identified for support of substantial equivalence for Heights of 3.0 and 4.0 mm.

The subject Interfaces are substantially equivalent to the BTI design cleared under K022258. Straumann Magellan™ Abutment System, cleared under K133421 is identified for support of prosthetic Ø3.5 mm, and On1 Concept for support of prosthetic Ø5 and Ø5.1 mm. Straumann® CARES® Golden Ti/TiN Abutments, cleared under K162848 is identified because it included similar surface treatment (Titanium Nitride, TiN) to that applied on subject Interfaces.

The subject Screws are substantially equivalent to that BTI screw design cleared under K022258 and K053355. DESS Dental Smart Solutions is identified for support of the DLC coating applied to the screw thread.

Table 5-3 Comparison of the *BTI Interna Narrow/Plus Dental Implant System UnicCa®* with the selected reference devices.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	SUBSTANTIAL EQUIVALENCE
	BTI Interna Narrow/Plus Dental Implant System UnicCa® (K211952)	**BTI Dental Implant System UnicCa® (K151391)**	**B.T.I. Biotechnology Institute, S.L. Dental Implant System (K022258)**	**BTI Interna Dental Implant System (K053355)**	**BTI Sterile Dental Drills Kit, BTI Abutments and Caps (K061383)**	
Product Classification	Product code: DZE, NHA Regulation No.: 21 CFR 872.3640Device Class II	Product code: DZE Regulation No.:21 CFR 872.3640. Device Class II	Product Code: DZE Regulation No.: 21 CFR 872.3430 Device Class II	Product Code: DZE Regulation No.: 21 CFR 872.3640 Device Class II	Product Code: NHA, EJL Regulation No.: 21 CFR 872.3630 and 21 CFR 873.3640 Device Class II	Identical.
Indications for Use	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants: These implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good	The BTI Dental Implant System UnicCa® for oral implant surgery is to be used for the partial or total replacement of teeth in edentulate patients. Once attached to the bone, the implants act as an anchor for various fixed or removable prosthetic solutions that can be used to improve or restore a patient's mastication function. In the case of 5.5 – 6.5mm long UnicCa® implants should be used in a two-stage surgical procedure. These implants are indicated for delayed loading. These implants are indicated only for straight abutments and to support permanently fixed restorations. In the case of Tiny® 3.0 UnicCa® implants: These implants shall be used only to replace maxillary lateral incisors and mandibular lateral and central incisors. Immediate loading is recommended when there is good primary stability	Dental implant system comprising endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures. The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.	Dental implant system comprising endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures. The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.	Dental burs are intended to drill bone tissue and provisionally soft tissues during, before and after a surgical intervention of dental implants. Endosseous dental implant abutments are intended to model the gingival tissue during the process of healing after the first or second surgery and to be attached to the implant to hold single or multiple teeth restorations.	Identical to primary predicate device.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	SUBSTANTIAL EQUIVALENCE
	BTI Interna Narrow/Plus Dental Implant System UnicCa® (K211952)	**BTI Dental Implant System UnicCa® (K151391)**	**B.T.I. Biotechnology Institute, S.L. Dental Implant System (K022258)**	**BTI Interna Dental Implant System (K053355)**	**BTI Sterile Dental Drills Kit, BTI Abutments and Caps (K061383)**	
	primary stability and an appropriate occlusal load.	and an appropriate occlusal load.				
Reason for predicate inclussion	-	Implant design and surface treatment	Healing abutment and Healing cap design, Interfaces, usage and screw design and material.	Definitive and Transepithelial abutment design, usage, connection to implant and materials used.	Transepithelial abutment design, sterilization and packaging	Similar designs, sterilization and packaging are included in subject and the identified predicate devices, intended for similar use.
Implant design						
Platform diameter (mm)	Interna Narrow: 3.5 Interna Universal Plus: 4.1	Interna: 4.1, 5.5 Externa: 3.5, 4.1, 5.5	Externa Narrow: 3.5 Externa Universal: 4.1 Externa Wide: 5.5	Interna Universal: 4.1 Interna Wide: 5.5	-	Similar. A new platform diameter for the Interna connection (Interna Narrow) is included. However, the range of implant platform diameters are covered by the identified predicate devices. Interna Universal Plus identical to the predicate device.
Implant length (mm)	Interna Narrow: 5.5 – 15 Interna Universal Plus: 7.5 – 11.5	5.5 – 18	7.0 – 18	7.0 – 18	-	Identical
Implant body diameter (mm)	Interna Narrow: 3.3 – 4.75 Interna Universal Plus: 6.0	Interna: 3.3 – 6.0 Externa: 3.0 – 5.5	3.3 – 5.5	3.3 – 5.0	-	Identical
Implant material	Commercially pure titanium (Grade 4)	Commercially pure titanium(Grade 4)	Commercially pure titanium (Grade 4)	Commercially pure titanium (Grade 4)	-	Identical.
Implant surface treatment	Calcium surface treatment	Calcium surface treatment	(not applicable)	(not applicable)	-	Identical to primary predicate.
Abutment design						
Restoration	Single and multiple	Single and multiple	Single and multiple	Single and multiple	Single and multiple	Identical.
Connection design	Engaging, non-engaging.	-	Engaging, non-engaging	Engaging, non-engaging	Engaging, non-engaging	Identical.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	SUBSTANTIAL EQUIVALENCE
	BTI Interna Narrow/Plus Dental Implant System UnicCa® (K211952)	**BTI Dental Implant System UnicCa® (K151391)**	**B.T.I. Biotechnology Institute, S.L. Dental Implant System (K022258)**	**BTI Interna Dental Implant System (K053355)**	**BTI Sterile Dental Drills Kit, BTI Abutments and Caps (K061383)**	
Abutment prosthetic diameter (mm)	3.5 – 5.1	-	3.5 – 6.5	4 – 6.5	4.1, 5.5	Similar. Range of diameters covered by the identified predicate devices.
Abutment gingival height (mm)	0.5 – 4	-	2 – 4	1 – 4	1 – 4	Similar. Range of gingival heights covered by the identified predicate devices and reference devices.
Abutment angulation	Straight (0º) (Except for Multi-im abutments that allow for up to 20º divergence per implant).	-	Straight (0º) (Divergence allowance not specified).	Straight (0º) (Divergence allowance not specified).	Straight (0º) (Divergence allowance not specified).	Identical. Divergence allowance in subject device is supported by bench testing provided.
Abutment material	Commercially pure titanium (Grade 4)	-	Commercially pure titanium (Grade 4), titanium Grade 3	Commercially pure titanium (Grade 4)	Commercially pure titanium (Grade 4)	Identical to identified predicate devices.
Prosthetic screws material	Ti6Al4V	-	Commercially pure titanium (Grade 4), gold/palladium alloy	Ti6Al4V	-	Identical to K053355.
Packaging, sterilization and shelf-life						
Implants and Healing screws	Provided sterile by gamma irradiation Packaging: Container (vial with clamp) Shelf-life: 5 years	Provided sterile by gamma irradiation Packaging: Container (vial with clamp) Shelf-life: 5 years	Primary (vial and blister) and Secondary (carboard box)	Primary (vial and blister) and Secondary (carboard box)	-	Identical to primary predicate device.

FEATURE	SUBJECT DEVICE	PREDICATE DEVICE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	ADDITIONAL PREDICATE	SUBSTANTIAL EQUIVALENCE
	BTI Interna Narrow/Plus Dental Implant System UnicCa® (K211952)	**BTI Dental Implant System UnicCa® (K151391)**	**B.T.I. Biotechnology Institute, S.L. Dental Implant System (K022258)**	**BTI Interna Dental Implant System (K053355)**	**BTI Sterile Dental Drills Kit, BTI Abutments and Caps (K061383)**	
Abutments	Healing abutments and Transepithelial abutments: Provided sterile by gamma irradiation. Packaging: Thermoform tray with peel top lid. Temporary Titanium abutments, Titanium abutments, Healing Caps, Aesthetic Interfaces and Screws: Provided non-sterile, to be sterilized by end user – moist heat. Packaging: thermosealed bag.	-	Temporary abutments, Titanium abutments, Healing Caps, Interfaces and Screws: Provided non-sterile. Packaging: thermosealed bag.	Temporary abutments, Titanium abutments, and Screws: Provided non-sterile, to be sterilized by end user – moist heat. Packaging: thermosealed bag.	Healing abutments and Transepithelial abutments: Provided sterile by gamma irradiation. Packaging: Thermoform tray with peel top lid	Similar packaging as the identified predicate devices.

7. PERFORMANCE TESTING

A series of non-clinical testing has been presented in order to demonstrate that the proposed device is substantially equivalent to the predicate devices. Tests performed are as follows:

- Biocompatibility testing in conformance with ISO 10993-1 *Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process.* All biological endpoints relative to a long-term implant as identified in the FDA guidance have been addressed with satisfactory results.
- Corrosion Testing, Surface Hydrophilicity and TOF·SIMS Analysis (leveraged from K151391).
- Fatigue Testing based on ISO 14801 *Dentistry. Implants. Dynamic fatigue test for endosseous dental implants* and FDA guidance document *Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments*, issued on May 12, 2004 has been evaluated for the BTI Interna Narrow/Plus Dental Implant System UnicCa®. Test results show that the proposed device is substantially equivalent to the predicate device for its intended use.
- Comparative area analyses for full external area and for bone resorption of up to 3 mm have been performed for subject implants and reference device. Additionally, immediate bone to implant contact per surgical protocol for these implants and reference device has been assessed. Results showed that subject device is substantially equivalent.
- Sterilization Validation to a sterility assurance level (SAL) of 10^{-6}, according to ISO 11137-1, ISO 11137-2 and ISO 17665-1.
- Packaging/Sterile Barrier/Shelf-Life validation according to ISO 11607-1, ISO 11607-2, ASTM F88, ASTM F1886, ASTM 1929 and ASTM F2096.
- Transport validation according to ISTA 3A.
- Endotoxin Testing according to ANSI/AAMI ST72 *Bacterial endotoxins- Test methods, routine monitoring, and alternatives to batch testing.*

8. CONCLUSIONS

The comparison of similarities and differences between the proposed range extension and the respective predicate devices demonstrate that the subject device is substantially equivalent to the identified predicate devices.