March 3, 2022

Implant Solutions PTY LTD (Osteon Medical)
℅ Melissa Burbage
Senior Regulatory Specialist
PaxMed International, LLC
12264 El Camino Real, Suite 400
San Diego, California 92130

Re: K212676
Trade/Device Name: Osteon Precision Milled Suprastructure
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: Class II
Product Code: NHA
Dated: January 28, 2022
Received: January 31, 2022

Dear Melissa Burbage:

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: 0MB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K212676

Device Name
Osteon Precision Milled Suprastructure

Indications for Use *(Describe)*

The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially orfully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments.

The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems:

- Nobel Biocare Multi Unit Abutment Plus, 4.8mm, max 30°
- Nobel Biocare Xeal Abutments, 4.8mm, max 30°
- Nobel Biocare Multi Unit Abutment, 4.8mm, max 30°
- MIS Multi-unit Abutments, 4.8mm
    - C1 Conical Connection Implant System, max 30°
    - V3 Conical Connection Implant System, max 30°
    - Internal Hex Implant System, max 30°
    - Conical Connection, max 30°
- Southern Compact Conical Abutments, 4.8mm
    - MAX Implant System, 0°
    - Provata Implant System, max 30°
    - Deep Conical (DC) Implants, 0°
    - Piccolo Implants, 0°
    - External Hex Implants, max 30°
- Astra Tech lmplant System® Multi Base Abutment EV, 4.8mm, max 30°
- Keystone Multi Unit Abutment, 4.8mm, 0°
- Neodent GM Mini Conical Abutment, 4.8mm, max 30°
- lmplant Direct GPS® Angled Abutment, 5.0mm, max 30°
- Dentium SuperLine® Abutments, 4.5-5.5mm, max 30°
- Zimmer Angled Tapered Abutments, 4.5mm, max 30°
- Paltop Multi Unit Abutment, 5.0mm, max 17°

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

The assigned 510(k) number is: K212676

1. Submitter's Identification:

Manufacturer: Implant Solutions PTY LTD (trading as Osteon Medical)
Address: 759-767 Springvale Road
Mulgrave, Victoria, 3170
Australia

Contact: Ms. Andrea Del Ciotto
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Phone Number: +61 408 583 222
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Date Summary Prepared: March 3, 2022

Official Correspondent: Melissa Burbage or Floyd G. Larson
PaxMed International. LLC
Phone Number: (858) 792-1235
Email: mburbage@paxmed.com or flarson@paxmed.com

2. Name of the Device:

Device Name(s): Osteon Precision Milled Suprastructure

Common Name: Overdenture Bar
Regulation Number: 21 CFR 872.3630
Regulation Name: Endosseous dental implant abutment
Regulatory Class: Class II
Product Code: NHA

3. Information for the 510(k) Cleared Device (Predicate Device):

Primary Predicate:
ISUS Implant Suprastructures (K122424)

Reference Device:
Panthera Dental Milled Bars (K173466)

Reference Devices for OEM Compatibilities
Multi-unit Abutment Plus, Nobel Biocare AB (K161416)
TiUltra Implants and Xeal Abutments, Nobel Biocare AB (K202344)
MIS C1 Narrow Platform Conical Connection Implant System and MIS C1 Wide Platform Conical Connection Abutments, MIS Implants Technologies Ltd. (K172505)
MIS V3 Conical Connection Dental Implant, MIS Implants Technologies Ltd. (K163349)
Conical Connection Implants, MIS Implants Technologies Ltd. (K112162)
MIS Internal Hex Dental Implant System, MIS Implants Technologies Ltd. (K180282)
Southern Implants MAX Implant System, Southern Implants (Pty) Ltd (K191054)
Provata Implant System, Paltop Advanced Dental Solution System K180465)
Deep Conical (DC) Implants and Accessories, Southern Implants (Pty) Ltd (K163060)
Piccolo Implants and Accessories, Southern Implants (Pty) Ltd (K173706)

External Hex Implants, Southern Implants (Pty) Ltd (K163634)
Multibase Abutments EV and ATLANTIS Suprastructures, Dentsply Sirona (K163350)
PrimaConnex Internal Connection Implant System, Lifecore Biomedical, Inc. (K051614)
Neodent Implant System - GM Line, JJGC Industria e Comercio de Materiais Dentarios SA (K163194)
GPS® Angled Abutment, Implant Direct Sybron Manufacturing, LLC (K153509)
Dentium Implantium® and SuperLine® Abutments, Dentium Company Limited (K141457)
Angled Tapered Abutment, Zimmer Dental, Inc. (K111853)
Paltop Advanced Dental Solution System, Paltop Advanced Dental Solutions Ltd. (K112795)

4. Device Description:

The Osteon Precision Milled Suprastructures (also referred as superstructures) are metallic dental restorative device that is intended for attaching by screw retention to dental abutments to aid in the treatment of partial and totally edentulous patients for the purpose of restoring their chewing function. These suprastructures attach to previously-cleared original equipment manufacturers (OEM) dental abutments using the (OEM) prosthetic screws. The abutment-borne subject devices are indicated for placement only on OEM implant/abutment constructs placed according to the labeling of the previously-cleared systems, and not to exceed the maximum angulation allowed for each OEM implant/abutment construct as identified in the Indications for Use Statement of the subject system.

The Osteon Precision Milled Suprastructure is designed for an individual patient from scans of the patient's impression. The suprastructure is manufactured in biocompatible Titanium alloy with the aid of Computer Aided Design (CAD) and Computer Aided Manufacturing (CAM) technology. All CAD/CAM fabrication is performed by Osteon Medical, within our premises.

Osteon Precision Milled Suprastructures facilitate the attachment of both removable and fixed dental prosthesis and hence categorized as type A and type B. The design specifications are listed in the table below.

- Type A: Intended to act as a supporting structure to facilitate the attachment of removable dental prosthesis and include: Primary Bar and Nexus Removable Bar.
- Type B: Intended to act as a supporting structure to facilitate the attachment of fixed dental prosthesis and include: Melbourne Bar and Nexus Fixed Bar

The table below presents the design specifications for two categories of suprastructures:

Description	**Type A (facilitates Removable Prosthesis)**		**Type B (facilitates Fixed Prosthesis)**	
	Minimum	Maximum	Minimum	Maximum
Total Cylinders	2	10	2	10
Suprastructure Span Between Cylinders (mm)	1	30	1	30
Suprastructure Height (mm)	3	12	3	22
Suprastructure Width (mm)	3.4	12	3.4	12
Distal Cantilever Section (mm)	0	15	0	15
Cylinder Height (mm)	0	4.6	0	4.6
Cylinder Diameter (mm)	4.5	8	4.5	8

5. Indications for Use:

The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments.

The Osteon Milled Suprastructure is indicated for compatibility with the following abutment systems:

- Nobel Biocare Multi Unit Abutment Plus, 4.8mm, max 30°
- Nobel Biocare Xeal Abutments, 4.8mm, max 30°
- Nobel Biocare Multi Unit Abutment, 4.8mm, max 30°
- MIS Multi-unit Abutments, 4.8mm
    - C1 Conical Connection Implant System, max 30°
    - V3 Conical Connection Implant System, max 30°
    - Internal Hex Implant System, max 30°
    - Conical Connection, max 30°
- Southern Compact Conical Abutments, 4.8mm
    - MAX Implant System, 0°
    - Provata Implant System, max 30°
    - Deep Conical (DC) Implants, 0°
    - Piccolo Implants, 0°
    - External Hex Implants, max 30°
- Astra Tech lmplant System® Multi Base Abutment EV, 4.8mm, max 30°
- Keystone Multi Unit Abutment, 4.8mm, 0°
- Neodent GM Mini Conical Abutment, 4.8mm, max 30°
- lmplant Direct GPS® Angled Abutment, 5.0mm, max 30°
- Dentium SuperLine® Abutments, 4.5-5.5mm, max 30°
- Zimmer Angled Tapered Abutments, 4.5mm, max 30°
- Paltop Multi Unit Abutment, 5.0mm, max 17°

6. Comparison to the 510(k) Cleared Devices (Predicate and Reference Devices):

Feature	1. Subject Device Osteon Precision Milled Suprastructure	2. Predicate Device ISUS Implant Suprastructure Primary Predicate K122424	2. Reference Device Panthera Dental Milled Bars Reference Device K173466	Similar or Different 1 vs 2
Regulation description	Endosseous dental implant abutment	Endosseous dental implant abutment	Endosseous dental implant abutment	Similar ✓
Indications for Use	The Osteon Precision Milled Suprastructure is indicated for attachment to dental abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. The Osteon Precision Milled Suprastructures are intended for attachment to a minimum of two (2) abutments. The Osteon Precision Milled Suprastructures are indicated for compatibility with the following abutment systems: ● Nobel Biocare Multi Unit Abutment Plus, 4.8mm, max 30° ● Nobel Biocare Xeal Abutments, 4.8mm, max 30° ● Nobel Biocare Multi Unit Abutment, 4.8mm, max 30° ● MIS Multi-unit Abutments, 4.8mm ○ C1 Conical Connection Implant System, max 30° ○ V3 Conical Connection Implant System, max 30° ○ Internal Hex Implant System, max 30° ○ Conical Connection, max 30° ● Southern Compact Conical Abutments, 4.8mm ○ MAX Implant System, 0° ○ Provata Implant System, max 30° ○ Deep Conical (DC) Implants, 0° ○ Piccolo Implants, 0° ○ External Hex Implants, max 30° ● Astra Tech Implant System® Multi Base Abutment EV, 4.8mm, max 30° ● Keystone Multi Unit Abutment, 4.8mm, 0° ● Neodent GM Mini Conical Abutment, 4.8mm, max 30° ● Implant Direct GPS® Angled Abutment, 5.0mm, max 30°	The ISUS Implant Suprastructures are indicated for attachment to dental implants or abutments in the treatment of partially or totally edentulous jaws for the purpose of restoring chewing function. The ISUS Implant Suprastructures are intended for attachment to a minimum of two (2) implants. The ISUS Implant suprastructures are indicated for compatibility with the following implant and abutment systems: Implants: ● Nobel Biocare Replace Select: NP (3.5mm), RP (4.3mm), WP (5.0mm), and Replace Select 6.0mm ● Nobel Biocare Active Internal: NP (3.5mm), RP (4.3mm, 5.0mm) ● Zimmer Screw Vent: D3.5, D4.5, D5.7 ● Straumann: NN (3.5mm), RN (4.8mm), WN (6.0mm) ● Straumann Bone Level: NC (3.3mm), RC (4.1 mm, 4.8mm) ● 3I Internal Connection: D3.4, D4.1, D5, D6 ● Friadent XiVE S: D3, D3.4, D3.8, D4.5, D5.5 Abutments: ● ASTRA TECH 20° and 45° UniAbutment ● ASTRA TECH UniAbutment EV: 3.6 ● ANKYLOS Balance Base Abutment D5.5 and Narrow Abutment D4.2 ● Nobel Biocare Multi -Unit Abutment RP: 4.0 mm ● Zimmer Tapered Abutment: 4.5mm ● Straumann RN (4.8mm), WN (6.5 mm) ● Straumann Bone Level: Multi-Base Abutment D3.5, D4.5	As an accessory to an endosseous dental implant to support a prosthetic device in a partially or edentulous patient. It is intended for use to support multiple tooth prostheses in the mandible or maxilla. The prostheses can be screw retained. Compatibility with the Zimmer Tapered Screw-Vent System for sizes 3.5 and 4.5.	Similar ✓ (1 – See below)

Feature	1. Subject Device Osteon Precision Milled Suprastructure	2. Predicate Device ISUS Implant Suprastructure Primary Predicate K122424	2. Reference Device Panthera Dental Milled Bars Reference Device K173466	Similar or Different 1 vs 2
	• Dentium SuperLine® Abutments, 4.5-5.5mm, max 30° • Zimmer Angled Tapered Abutments, 4.5mm, max 30° • Paltop Multi Unit Abutment, 5.0mm, max 17°	• Straumann Bone Level Angled Abutment:4.0 mm • 3I Low Profile Abutment • Friadent XiVE MP D3.8, D4.5, D5.5 • Friadent XiVE TG 03.8, 04.5, 05.5		
Device Material	Titanium alloy Ti-6Al- 4V Single milling blocks	Commercially-Pure (CP) Titanium and Cobalt-Chromium alloy Single milling blocks	Titanium alloy Ti-6Al- 4V	Similar ✓ (2 – See below)
Design/ Technology	CAD/CAM milling from single milling blanks.	CAD/CAM milling from single milling blanks	CAD/CAM milling from single milling blanks.	Similar ✓
Fixation Method	Abutment-borne	Implant-borne or abutment-borne	Implant-borne	Similar ✓
Design/ Construction	Patient specific/ machined	Patient specific/ machined	Patient specific/ machined	Similar ✓
Sterility	Supplied Nonsterile	Supplied Nonsterile	Supplied Nonsterile	Similar ✓
Target population	Adult patients	Adult patients	Adult patients	Similar ✓
Prescription/ OTC	Prescription only	Prescription only	Prescription only	Similar ✓
Recommended Cleaning and Maintenance	Proper oral hygiene	Proper oral hygiene	Proper oral hygiene	Similar ✓
Design specifications	See tables below	See tables below	See tables below	Similar ✓ (3 – See below)

(1) Indications for Use: Subject, predicate device, and reference device are indicated for attachment to dental implants or abutments in the treatment of partially or fully edentulous jaws for the purpose of restoring chewing function. Subject device is similar to primary predicate (K122424) and listed all compatible abutments and implants systems, however reference device (K173466) is compatible to only one implant system. The differences in OEM compatibilities have been addressed by the identification of the reference devices (identified in Reference Devices for OEM Compatibilities) as well as by the reverse-engineering/dimensional analysis provided.

(2) Device Material: Material of subject device is same as reference device(K173466).

(3) Design specifications: Same as reference device (K173466). Relevant information not visible for primary predicate (K122424). See following two tables below for data.

Table 2: Comparison chart of design parameters for Type A Suprastructure (removable prosthesis) with primary and reference devices

Design Parameter	1. Subject Device Osteon Precision Milled Suprastructure		2. Predicate Device ISUS Implant Suprastructure Primary Predicate K122424		2. Reference Device Panthera Dental Milled Bars Reference DeviceK173466		Similar or Different 1 vs 2
	Min	Max	Min	Max	Min	Max	
Total Cylinders	2	10	2	Not available	2	10	Similar ✓ (4 – See below)
Suprastructure/Bar Span between Cylinders	1mm	30mm	Not available	Not available	0mm	30mm	Similar ✓ (5 – See below)
Suprastructure/Bar Height	3mm	12mm	Not available	Not available	2.5mm	8mm	Similar ✓ (6 – See below)
Suprastructure/Bar Width	3.4mm	12mm	Not available	Not available	1.5mm	12mm	Similar ✓ (5 – See below)
Distal Cantilever Section/ Distal Extension	0mm	15mm	Not available	Not available	0mm	30mm	Similar ✓ (5 – See below)
Cylinder Height	0mm	4.6mm	Not available	Not available	0mm	10mm	Similar ✓ (5 – See below)
Cylinder Diameter	4.5mm	8mm	Not available	Not available	3mm	8mm	Similar ✓ (5 – See below)

(4) Same as reference device (K173466). Minimum no of cylinders (and therefore implants/abutments) the device supports is same as primary predicate (K122424).

(5) Osteon device dimension falls within range specified for reference device (K173466). Relevant information not visible for primary predicate (K122424). This will have no impact on safety and efficacy.

(6) Osteon devices can support wider suprastructure/bar height than specified for reference device (K173466). Relevant information not visible for primary predicate (K122424). This will have no impact on safety and efficacy as Osteon devices dimension allows more material making it more stable.

Table 3: Comparison chart of design parameters for Type B Suprastructure (Fixed prosthesis) with primary predicate and reference devices

Design Parameter	1. Subject Device Osteon Precision Milled Suprastructure		2. Predicate Device ISUS Implant Suprastructure Primary Predicate K122424		2. Reference Device Panthera Dental Milled Bars Reference DeviceK173466		Similar or Different 1 vs 2
	Min	Max	Min	Max	Min	Max	
Total cylinders	2	10	2	Not available	2	10	Similar ✓ (7 – See below)
Suprastructure/Bar Span between Cylinders	1mm	30mm	Not available	Not available	0mm	30mm	Similar ✓ (8 – See below)
Suprastructure/Bar Height	3mm	22mm	Not available	Not available	3.5mm	22mm	Similar ✓ (9 – See below)
Suprastructure/Bar Width	3.4mm	12mm	Not available	Not available	2.5mm	10mm	Similar ✓ (10 – See below).
Distal Cantilever Section/ Distal Extension	0mm	15mm	Not available	Not available	0mm	30mm	Similar ✓ (8 – See below)
Cylinder Height	0mm	4.6mm	Not available	Not available	Not available	Not available	Design parameter not specified for primary predicate and reference devices.
Cylinder Diameter	4.5mm	8mm	Not available	Not available	Not available	Not available	Design parameter not specified for primary predicate and reference devices.

(7) Same as reference device (K173466). Minimum no of cylinders (and therefore implants/abutments) the device can support is same as primary predicate (K122424).
(8) Osteon device dimension falls within range specified for reference device(K173466). Relevant information not visible for primary predicate (K122424). This will have no impact on safety and efficacy.
(9) Osteon devices allow wider suprastructure/bar height than reference device (K173466). This will have no impact on safety and efficacy.
(10) Osteon device can have maximum suprastructures width higher than reference device (K173466). Relevant information not visible for primary predicate (K122424). This will have no impact on safety and efficacy as Osteon devices dimension allows more material making it more stable.

7. Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:

The following section contains discussion of the non-clinical tests performed for the determination of substantial equivalence to predicate and reference devices. The non-clinical testing includes assessment of the physical properties of the bars and its ability to achieve its intended use. The bars meet the same specifications as set for the primary and reference devices.

Dimensional Analysis

Dimensional analysis (reverse-engineering) was provided to demonstrate compatibility with the identified OEM constructs.

Fatigue Testing

Fatigue testing was not performed since the subject devices are abutment-borne and are not intended to compensate for angulation in excess of the maximum angulation of OEM angled abutments in each reference device clearance, as outlined in the Indications for Use Statement.

Biocompatibility

Our patient contacting material is Titanium (Ti-6Al-4V) alloy and it is the same material as that of the Panthera predicate K173466. ISO 10993-5 Cytotoxicity testing was performed on the subject device. The patient contacting material conforms to the ASTM F136 Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI Alloy for Surgical Implant Application.

Sterilization

Osteon Precision Milled Suprastructure are provided non-sterile, and sterilization is to be conducted by end user prior to first use. Sterilization validation according to ISO 17665-1:2006 *Sterilization of health care products – Moist heat – Part 1: Requirements for the development, validation, and routine control of a sterilization process for medical devices* and ISO 17665-2 *Sterilization of health care products — Moist heat — Part 2: Guidance on the application of ANSI/AAMI/ISO 17665-1* was conducted for the Osteon Precision Milled Suprastructure. The validated pre-vacuum steam sterilization cycle is recommended to the end users and specified in the Instructions for Use.

Discussion of Clinical Tests Performed:

The indication for use for Osteon Precision Milled Suprastructure is same as that identified in the predicate and reference devices. The dimensions of Osteon Precision Milled Suprastructure are typical for dental restorative devices and same as other previously cleared devices under 510(k). In addition, the production process does not employ any novel technologies that is different from legally marketed dental restorative devices. Hence, Osteon Medical found it was not necessary to conduct human clinical study to support substantial equivalence.

Conclusion

The proposed device, Osteon Precision Milled Suprastructure, is similar to the predicate and reference devices based on the following – it has same intended use, indications for use, aimed for same user population, made of similar biocompatible materials, has equivalent technological characteristics and as such is improbable to increase or add new risks in the final device. The differences in subject, predicate, and reference devices were addressed with the non-clinical bench testing summarized above, as well as appropriate labeling mitigations to ensure adequate use of the device by the end-users. The data included in this submission demonstrate substantial equivalence to the predicate and reference devices listed above.