March 10, 2026

Institut Straumann AG
% Jennifer Jackson
Senior Director of Regulatory Affairs and Quality
Straumann USA, LLC
60 Minuteman Road
Andover, Massachusetts 01810

Re: K252168
Trade/Device Name: Straumann® BLC Implants - Indication Widening
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: July 8, 2025
Received: February 4, 2026

Dear Jennifer Jackson:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality Management System Regulation (QMSR) (21 CFR Part 820), which includes, but is not limited to, ISO 13485 clause 7.3 (Design controls), ISO 13485 clause 8.3 (Nonconforming product), and ISO 13485 clause 8.5 (Corrective and preventative action). Please note that regardless of whether a change requires premarket review, the QMSR requires device manufacturers to review and approve changes to device design and production (ISO 13485 clause 7.3 and 21 CFR 820.70) and document changes and approvals in the Medical Device File (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Management System Regulation (QMSR) (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 -S

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)*
K252168

Device Name

Straumann® BLC Implants – Indication Widening

Indications for Use *(Describe)*

Straumann® dental implants for use in the pterygoid region are indicated in cases of severe jaw resorption for the functional and esthetic oral rehabilitation of the upper jaw in edentulous or partially edentulous patients. This indication is limited to Straumann® BLC bone-level implants with a length of 18 mm and a diameter of 3.75 mm (RB platform). Implants anchored in the pterygoid region shall be placed using a free-hand surgical technique and restored only in splinted applications utilizing at least two implants in combination with screw retained abutments.

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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15 510(k) Summary

15.1 Submitter's Contact Information

Submitter:	Straumann USA, LLC (on behalf of Institut Straumann AG) 60 Minuteman Road Andover, MA 01810 Registration No.: 1222315 Owner/Operator No.: 9005052 On the behalf of: Institut Straumann AG Peter Merian-Weg 12 4052 Basel, Switzerland
Contact Person:	Jennifer M. Jackson, MS, RAC Sr. Director, Regulatory Affairs and Quality Phone Number: +1-978-747-2509 Fax Number: +1-978-747-0023
Prepared By & Alternate Contact:	Jose Vitor Araujo Senior Regulatory Affairs and Compliance Manager Institut Straumann AG Phone number: +41 61 965 1217
Date of Submission:	10 March 2026

15.2 Name of the Device

Trade Names:	Straumann® BLC Implants
Common Name:	Endosseous Dental Implant
Classification Name:	Endosseous Dental Implant
Regulation Number:	§872.3640
Device Classification :	II
Product Code(s):	DZE
Classification Panel:	Dental

15.3 Predicate Device(s)

Primary Predicate:

- *K212785 - Blue Sky Bio Implant System*

Reference Devices:

- *K230108 - Straumann® BLC and TLC Implants*
- *K190662 - MRI Compatibility for Existing Straumann Dental Implant Systems*

15.4 Device Description

The subject devices are part of the Straumann® Dental Implant System, which is an integrated system of endosseous dental implants with corresponding abutments and healing components as well as instruments and prosthetic parts. Straumann® dental implants are solid screw implants with a bone anchorage surface that is large-grit sandblasted and acid-etched. Straumann® dental implants can be used following the extraction or loss of natural teeth to restore chewing function. Within the scope of this submission, the Straumann® BLC bone-level implants (diameter 3.75 mm, length 18 mm) are intended for surgical placement in the pterygoid region of the maxilla to provide posterior support for multi-unit, splinted prosthetic restorations. The implants are to be used only in combination with compatible screw-retained angled abutments (17° or 30°) and are not intended for single-unit or single-tooth restorations.

This premarket notification seeks to expand the previously cleared indications for use of the Straumann® BLC implants (K230108) to include anchorage in the pterygoid region, without changes to the fundamental device design, materials, surface characteristics, or implant-abutment connection.

The subject BLC implants indicated for the pterygoid application are provided in a single prosthetic platform identified as RB (Regular Base) for Ø 3.75 mm diameter implant (18 mm length only).

15.5 Intended Use

Straumann® dental implants and abutments are intended for oral implantation to provide a support structure for connected prosthetic devices.

15.6 Indications for Use

Straumann® dental implants for use in the pterygoid region are indicated in cases of severe jaw resorption for the functional and esthetic oral rehabilitation of the upper jaw in edentulous or partially edentulous patients. This indication is limited to Straumann® BLC bone-level implants with a length of 18 mm and a diameter of 3.75 mm (RB platform). Implants anchored in the pterygoid region shall be placed using a free-hand surgical technique and restored only in splinted applications utilizing at least two implants in combination with screw retained abutments.

15.7 Technological Characteristics

The technological characteristics of the subject devices are compared to the primary predicate and reference devices in the Table 15-1:

Table 15-1 – Comparison matrix: subject device versus primary predicate and reference device

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE	REFERENCE DEVICE
K Number/ name	**510(k) Number not yet known**	**K212785 Blue Sky Bio Implant System BIO|LONG IMPLANTS and BIO|MAX MULTI-ONE**	**K230108 Straumann® BLC and TLC Implants**
Indications for Use	Straumann® dental implants for use in the pterygoid region are indicated in cases of severe jaw resorption for the functional and esthetic oral rehabilitation of the upper jaw in edentulous or partially edentulous patients. This indication is limited to Straumann® BLC bone-level implants with a length of 18 mm and a diameter of 3.75 mm (RB platform). Implants anchored in the pterygoid region shall be placed using a free-hand surgical technique and restored only in splinted applications utilizing at least two implants in combination with screw retained abutments.	Blue Sky Bio Long Implant System is intended for surgical placement in the bone of the upper jaw to provide support for prosthetic devices, such as artificial teeth, to restore chewing function. Implants may be used with single-stage or two-stage procedures, and may be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Long implants can be placed bicortically in cases of reduced bone density. Blue Sky Bio Long implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Blue Sky Bio Long Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function. Blue Sky Bio Multi One Implant System is intended for surgical placement in the bone of the upper or lower jaw to provide support for prosthetic devices to restore chewing function. Implants may be used with single-stage or two-stage procedures. They can be loaded immediately when good primary stability is achieved and with appropriate occlusal loading. Blue Sky Bio Multi One Implants are indicated for multi- unit restorations in splinted applications. Blue Sky Bio Multi One Implant System with a 45º angulation are indicated for surgical installation in the pterygoid region only, in cases of severe jaw resorption, in order to restore patient esthetics and chewing function.	Straumann® dental implants are indicated for the functional and esthetic oral rehabilitation of the upper or lower jaw of edentulous or partially edentulous patients. They can be used for immediate, early or late implantation following the extraction or loss of natural teeth. The implants can be placed with immediate function for single-tooth and/or multiple tooth restorations when good primary stability is achieved and with appropriate occlusal loading to restore chewing function.
Material	Titanium-13 Zirconium alloy (Roxolid®)	Titanium alloy (Ti-6Al-4V)	Titanium-13 Zirconium alloy (Roxolid®)
Surface Treatment	Hydrophilic SLActive® and SLA®	Grit blasted and acid etched	Hydrophilic SLActive® and SLA®
Implant to Abutment Connection	TorcFit (with conical fitting)	<u>BIO|LONG IMPLANTS</u> Internal hex with 12° taper Internal hex with 45° bevel <u>BIO|MAX MULTI-ONE IMPLANTS</u> One-piece	TorcFit (with conical fitting)
Implant Diameter and Length	<u>BLC implants:</u> ø 3.75 mm, 18 mm	<u>BIO|LONG IMPLANTS</u> Ø 3.7: 20, 22.5, 25 mm Ø 4.3: 20, 22.5, 25 mm Ø 5.0: 20, 22.5, 25 mm <u>BIO|MAX MULTI-ONE IMPLANTS</u> Ø 3.5 (45º used in pterygoid placement only): 10, 11.5, 13, 16, 18 and 20 mm Ø 3.7 (17º, 30º and 45º- 45º used in pterygoid placement only): 20, 22.5 and 25 mm Ø 4.3 (45º used in pterygoid placement only): 10, 11.5, 13, 16, 18, 20, 22.5 and 25 mm Ø 4.3 (17º and 30º): 20, 22.5 and 25 mm Ø 5.0 (17º, 30º and 45º - 45º used in pterygoid placement only): 20, 22.5 and 25 mm	<u>BLC implants:</u> Ø 3.3: 8, 10, 12, 14, 16, 18 mm Ø 3.75 and 4.5: 6, 8, 10, 12, 14, 16, 18 mm Ø 5.5: 6, 8, 10, 12, 14, 16mm Ø 6.5: 6, 8, 10, 12, 14 mm <u>TLC implants:</u> Ø 3.3: 8, 10, 12, 14, 16, 18 mm (S and SP) Ø3.75 and 4.5: 6, 8, 10, 12, 14, 16, 18 mm (S and SP) Ø 5.5: 6, 8, 10, 12 mm (S and SP) Ø 6.5: 6 mm (S and SP) Ø 6.5: 8 and 10 mm (SP only)
Angulation	<u>BLC implants:</u> Prosthetic angulation achieved via two-piece, screw-retained abutments in 17° and 30° angles.	<u>BIO|LONG IMPLANTS (Abutment angle)</u> Straight, 12°, 17°, 24°, 30°, 45° (45°used in Pterygoid placement only) <u>BIO|MAX MULTI-ONE IMPLANTS</u> Straight, 17°, 30°, 45° (45º used in pterygoid placement only)	<u>BLC & TLC implants:</u> Prosthetic angulation via angled abutments (17°, 30°) among other prosthetic offerings for single and multiple tooth restorations
Implant Design	Apically tapered Bone Level implant	<u>BIO|LONG IMPLANTS</u> Threaded root-form implant to be used with mating abutments <u>BIO|MAX MULTI-ONE IMPLANTS</u> One-piece implant/abutment	Apically tapered Bone Level implant and Apically tapered Tissue Level implant

Traditional 510(k) Submission

Straumann® BLC Implants – Indication Widening

510(k) Summary

FEATURE	PROPOSED DEVICE	PRIMARY PREDICATE	REFERENCE DEVICE
K Number/ name	**510(k) Number not yet known**	**K212785 Blue Sky Bio Implant System BIO|LONG IMPLANTS and BIO|MAX MULTI-ONE**	**K230108 Straumann® BLC and TLC Implants**
Thread Pitch	BLC implants: Ø 3.75 mm: 0.8 mm	-	0.8, 0.9, 1 and 1.15 mm
Sterilization Method	Irradiation	Irradiation	Irradiation
Literature Review to Support Anchorage in the Pterygoid region	Clinical literature is submitted in support of the subject device use in the pterygoid region under the proposed conditions of use (splinted, screw-retained restorations). The revised clinical literature review is aligned to the subject device configuration by focusing on pterygoid implants with diameter and length consistent with the submission (Ø3.75 mm and 18 mm), and by documenting outcomes under steep placement trajectories (typically ≥50°) and prosthetic correction using angled abutments. The review includes ≥12-month post-loading clinical performance outcomes (implant survival, marginal bone loss, and complications) in patient populations representative of complex posterior maxillary rehabilitation.	Clinical literature was submitted in support of the subject implant placement in the pterygoid region and implant dimensions. Clinical literature in the summary reported on implant diameters covering those of the subject devices (Ø3.5-5.0mm with lengths of 10-25mm) for pterygoid placement[2].	-

[2] K212785 510(k) Premarket Notification Summary

The subject device indications for use are substantially equivalent to those of the predicate device. Both describe pterygoid region use with splinted restorations requiring multiple implants and are indicated for patients with severe jaw resorption. The subject device includes additional conservative restrictions (e.g., screw-retained abutments only) that do not raise new questions of safety or effectiveness. Therefore, the differences in language do not affect the intended use or performance and support a determination of substantial equivalence. The Indication for Use of the primary predicate device includes details on angulation, whereas for the subject devices, those details are provided in the Compatibility Information section.

The subject device has identical or equivalent technological characteristics compared to the primary predicate and reference devices. The material, surface treatment, sterilization method, and implant characteristics (length, diameter and connection) are equivalent to the primary predicate and reference devices. Also, the subject device incorporates a threaded implant body with an apically tapered geometry designed to achieve primary stability during placement. The predicate device (K212785) similarly utilizes threaded root-form implants intended for mechanical retention within bone. While specific design characteristics such as thread geometry (e.g., pitch, depth, or profile) may differ between systems, both implants employ threaded designs to achieve primary stability and mechanical fixation within bone. Bench testing evaluating insertion torque demonstrates that the subject devices perform as intended under the proposed conditions of use and do not raise new questions of safety or effectiveness. The device performance demonstrates substantial equivalence between subject devices and primary predicate/reference devices.

15.8 Performance Testing

15.8.1 Sterilization Validation and Shelf Life

There are no changes to the sterilization by gamma irradiation procedures or processes from those of the Straumann reference devices cleared under K230108. The subject devices do not represent a higher challenge to the sterilization process in comparison to the validated worst-case product and validated gamma irradiation sterilization process. The subject devices are following the FDA guidance - Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile, issued on 21 January 2016.

The implants will be provided sterile via gamma irradiation at a dose of minimum 25 kilogray (2.5 Mrad) and will be terminally sterilized after packaging. The validation method used was the VDmax25. A sterility assurance level (SAL) of 10^{-6} had been validated in accordance with ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices, 2006-04-05 and ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose (see attached Validation report_Sterilization by Gamma). These are the identical validation methods used for the Straumann reference devices cleared under K230108.

A full validation of the new sterilization cycles by X-ray irradiation were performed per ISO 11137-1:2006, Sterilization of health care products – Radiation – Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices and ISO 11137-2:2013, Sterilization of health care products – Radiation – Part 2: Establishing the sterilization dose. The validation method used was the VDmax25. A sterility assurance level (SAL) of 10^{-6} had been validated for a minimum dose of 25 kilogray. Two cycles were validated to account for different pallet configurations during routine sterilization.

The packaging of the subject device is equivalent to the packaging of the primary predicate and reference device. The shelf life for devices provided sterile is 5 years.

The devices will not be marketed as non-pyrogenic. Pyrogenicity information provided is based on FDA Guidance on “Submission and Review of Sterility Information in Premarket Notification (510(k)) Submission for Devices Labeled as Sterile, issued on 21 January 2016.” The method used to determine the device meets pyrogen limit specifications is LAL Endotoxin Analysis with testing limit of 20 EU/device, based on a blood contacting and implanted device.

15.8.2 Biocompatibility Testing

Biological assessment has been performed according to ISO 10993-1 “Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process” and to the FDA Guidance document “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process’, Guidance for Industry and Food and Drug Administration Staff, Document issued on: June 16, 2016” for each of the subject devices.

The subject devices are equivalent in material, surface, manufacturing processes, sterilization process, body contact and contact duration to the reference device K230108 therefore, no new issues regarding biocompatibility were raised.

In addition to bridging to the reference device K230108, new biocompatibility testing was performed to support X-ray irradiation as an alternative sterilization method. Testing included in vitro cytotoxicity (MTT) and chemical characterization for volatile and semi-volatile compounds (GC-MS and headspace GC-MS/FID) on representative devices at T0 (no aging), T3 (3-year accelerated aging), and T5 (5-year accelerated aging). All extracts met cytotoxicity acceptance criteria, no new or unexpected leachables were identified at toxicologically relevant levels, and no new biological risks were observed compared to the gamma-sterilized reference device, supporting the biological safety of the subject devices sterilized by X-ray irradiation.

15.8.3 Electromagnetic Compatibility

There are no significant changes to the materials and dimensions from the currently marketed reference devices. Therefore, no new issues of electromagnetic compatibility are raised for the subject devices, and they can be considered MR Conditional.

The subject implants have obtained the status of MR Conditional per K230108 and K190662. The MR Conditional tests were conducted according to FDA's Guidance "Testing and Labeling Medical Devices for Safety in Magnetic Resonance (MR) Environment".

15.8.4 Performance Testing – Bench Testing

Dynamic fatigue performance of the subject Straumann BLC implants in the pterygoid indication is supported by bench testing previously reviewed and cleared under K230108, as the implant designs, materials, and connection geometries are identical." The testing was conducted according to the FDA guidance document "Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Abutments" and ISO 14801 "Dentistry — Implants — Dynamic loading test for endosseous dental implants". The test was conducted in saline (2 Hz and 37°C) at 2 million cycles, covering permanent restoration of the implant without failure.

Insertion tests were performed to evaluate the primary stability of the subject implants when placed in bone models representative of the pterygoid region. These tests considered both cortical thickness and implant dimensions, using synthetic polyurethane plates simulating the anatomical characteristics of the pterygoid plate. An insertion torque range was defined using published literature to establish a lower limit (risk of implant loss because of insufficient primary stability) and an upper limit (risk of potential bone resorption, bone overload). The average insertion torque for the tested implant met this predefined acceptance criteria. These results demonstrate that the subject devices perform as intended under the proposed conditions of use and do not raise new questions of safety or effectiveness.

An assessment of bone-to-implant contact (BIC) was included in the previously cleared 510(k) notification K230108. The nominal endosseous surface area of the subject devices was calculated and documented. The analysis demonstrated that the subject implants offer a large endosseous surface. The acceptance criterion for surface area and BIC was met as part of that prior evaluation.

Scanning electron microscopy and light microscopy examinations of the apical end of the implant body after removal from the packaging was previously submitted and reviewed under K230108 for identical implant designs and packaging systems, and is therefore leveraged to support the subject devices in this K252168 submission. All the inspected implants showed a uniform breaking surface, with no residual metal fragments at the broken tip area.

The subject device surface treatments are identical to the surface treatments of the reference devices cleared under K230108. The SLActive® and SLA® surfaces are both sand-blasted, large-grit and acid-etched.

15.9 Clinical Literature Review

A comprehensive review of clinical literature was conducted to support the use of Straumann® BLC implants with a length of 18 mm and a diameter of 3.75 mm in the pterygoid region. Two independent literature searches were performed in February and March 2025, respectively. Search one used the search terms (dental implant) AND (pterygoid). The search was limited to abstract, full text, humans, English and Portuguese without any restriction on time. Search two was performed on PubMed and EMBASE using the search terms: Pterygoid implants, Pterygomaxillary implants, Pterygoid plate implants, Tuberosity implants, Tuberosity maxilla without any limits to type, subject or language of publication, but only looking back to 2017, the year the predicate device was registered. Results of the two searches were combined, duplicates removed and remaining publications used for data extraction and analysis. This literature review includes those publications that report on devices comparable to the subject Straumann® BLC Implants (diameter 3.75 mm and 18 mm length), and intended for use in splinted, screw-retained restorations with angled abutments (17° and 30°) in patients with severe posterior maxillary resorption.

The selected literature describes the clinical experience with implants placed bi-cortically in the pterygoid region for the rehabilitation of atrophic maxillae. Across the reviewed studies, the implants were placed with posterior angulation targeting the pterygomaxillary junction, commonly engaging dense cortical bone for primary stability. The reported implant geometries and surgical approaches are consistent with the configuration of the subject devices.

Pterygoid placement techniques routinely involve angled trajectories that are later corrected at the prosthetic level. The use of angled abutments, including 17° and 30° options, is widely documented and reflects standard clinical practice. These angulations provide prosthetically accessible screw channels while maintaining occlusal stability in full-arch and posterior segmental restorations.

All implants in the reviewed literature were used in splinted restorations, reflecting the loading conditions under which the subject devices are intended to be used. This configuration is recognized for minimizing bending moments on individual implants and enhancing fatigue performance over time.

The literature consistently reports high implant survival rates, predictable bone preservation, and positive patient outcomes in terms of function and comfort. These results were achieved using implants with comparable designs and dimensions to the subject device, supporting the mechanical and clinical suitability for pterygoid anchorage.

In summary, the published evidence demonstrates that implants of the type and dimensions represented by the Straumann BLC subject device can be successfully used in the pterygoid region. When placed at appropriate angulations and restored with splinted, screw-retained prostheses, the subject device falls well within the range of successful clinical configurations documented in the literature. These findings support the expanded indication proposed in this submission and do not raise new questions of safety or effectiveness

Table 15-2. Summary of Clinical Literature supporting the use of implants in the pterygoid region

Reference	Study type	Study details	Indication	Patient/Devices						Mean Follow-up	Implant survival/success	Prosthesis survival/ success	Adverse events	Bone loss	Patient related outcomes	Aspect supported	Comments
				No of patients	No and type of pterygoid implants used (manufacturer)	Implant length	Implant diameter	Implant insertion angle	Angulation of abutment								
Curi MM, Cardoso CL, Ribeiro KdCB. Retrospective study of pterygoid implants in the atrophic posterior maxilla: implant and prosthesis survival rates up to 3 years. The International journal of oral & maxillofacial implants. 2015 30(2): pp. 378–383 [5]	retrospective study	Patients with an atrophic posterior maxilla rehabilitated with pterygoid implants between 1999 and 2010 and followed for at least 36 months after implant loading. Two outcome variables were considered: implant success and prosthesis success.	34 were fixed partial prostheses and 22 were fixed full-arch (complete) prostheses. Forty were metal-ceramic and 16 were acrylic resin the healing period before implants were loaded was approx. 3-4 months	66	66 Branemark System, MKIII (Nobel Biocare)	**18mm (38 implants)** 20mm (28 implants)	**3.75mm (43 implants)** 4.0 mm (23 implants)	15 degrees (6 implants) 30 degrees (14 implants) 60 degrees (12 implants) 45 degrees (34 implants)	**17 degrees** or standard abutments	3 years	Success: 99% Survival: 97% to 100%	Survival: 100% for fixed partial dentures 97.7% for full-arch dentures	1 implant failure due to lack of osseointegration	1.21 mm (1.31 mm mesially 1.01 mm distally).		Implant length (18 mm) Implant diameter (3.75) angulated abutment (17° and/or 30°) full or partial edentulism splinted application (min. 2 implants) implant insertion angle (≥50 degrees relative to Frankfort plane) drilling protocol (no osteotomes)	This study supports the following aspects of the subject devices: implant design (length and diameter), the use of angulated abutments, the use in partially or fully edentulous patients in a splinted application, implant insertion at angles ≥50° in relation to the Frankfort plane; placement by a drill-based osteotomy without the use of osteotomes.
Rodríguez X, Méndez V, Vela X, Segalà M. Modified surgical protocol for placing implants in the pterygomaxillary region: clinical and radiologic study of 454 implants. The International journal of oral & maxillofacial implants. 2012 Nov-Dec; 27(6):1547–53 [6]	retrospective study	To review a series of 454 pterygoid implants placed more vertically than the previous standard angle (45 degrees) over a functional loading period ranging from 2 months to 14 years with a mean follow-up period of 6 years.	313 metal-ceramic multifixture partial-arch fixed prostheses, 38 metal-ceramic multifixture complete-arch fixed prostheses, 17 hybrid multifixture complete-arch fixed prostheses, 13 complete removable overdentures, and 11 partial fixed prostheses connected to the teeth.	392	454 pterygoid: 453 Osseotite (3i/Imolant Innovations) 1 Mis (Israel DVDent)	20mm (51 implants) **18mm (349 implants)** 15mm (45 implants) 13mm (9 implants)	**Ø3.75mm (448 implants)** Ø4.0 mm (5 implants) Ø4.2 mm (1 implant)	The mean mesiodistal angulation of the pterygoid implants was 70.4 degrees ± 7.2 (range 47 to 90 degrees) 94.7% showed an **implant mesiodistal angulation between 60 and 90 degrees**	not specified	2 months to 14 years (average 6 years)	Survival: 96.5%	not described	16 implant failures Intraoperative: Four cases of hemorrhage three cases of pain Postoperative: One case of transient hypoesthesia of the palatine nerve lasting 4 weeks one case of pterygomaxillary pain that needed the implant removed. Prosthetic: One patient that exhibited bruxism fractured two bilateral	Not measured		Implant length (18 mm) Implant diameter (3.75) full or partial edentulism splinted application (≥ 2 implants) implant insertion angle (≥50 degrees relative to Frankfort plane) drilling protocol (no osteotomes)	This study supports the following aspects of the subject devices: implant design (length and diameter), the use in partially or fully edentulous patients in a splinted application, implant insertion at angles ≥50° in relation to the Frankfort plane; placement by a drill-based osteotomy without the use of osteotomes.

													pterygoid implants after 5 years of loading. It must be noted that this patient also fractured the implants placed in the premolar region. Three bruxism patients also fractured the hybrid prosthesis				
Total numbers for key parameters (Clinical Studies >10 patients)				**458**	**520**	**13 mm to 20 mm**	**3.75 mm to 4.2 mm**	**15° to 90°**	**from 17°**	**up to 14 years**	**survival: 96.5% to 100% success: 99%**	**n/a**	**n/a**	**1.21 mm**	**n/a**		

15.10 Conclusion

The documentation submitted in this premarket notification demonstrates that the subject devices are substantially equivalent to the primary predicate and reference devices.