April 1, 2024

Southern Implants (Pty) Ltd
Jade Rawlins
Design Engineer
1 Albert Road
Irene, Gauteng 0062
SOUTH AFRICA

Re: K232726
Trade/Device Name: External Hex Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE
Dated: February 28, 2024
Received: March 4, 2024

Dear Jade Rawlins:

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 System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (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 systems (QS) regulation (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.

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)*
K232726

Device Name
External Hex Implant System

Indications for Use *(Describe)*

For Standard Length IBR36d Implant Range:
Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

When using Southern Implants' Standard Length IBR36D Implants with angulation of 36° a minimum of 4 implants must be used and splinted

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

For Extra Length IBR36d Implant Range:
Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Extra Length IBR36d Implants can be placed bicortically in cases of reduced bone density.
Extra Length IBR36d Implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Extra Length IBR36d Implants 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.

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

For Extra Length IBR24d Implant Range:
Southern Implants' External Hex Implants are intended for surgical placement in the upper jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Southern Implants' Extra Length IBR24d Implant Range when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

K232726

510(k) Summary

External Hex Implant System

Southern Implants (Pty) Ltd

1st April, 2024

ADMINISTRATIVE INFORMATION

Manufacturer Name	Southern Implants (Pty) Ltd 1 Albert Road Irene, Gauteng, 0062 South Africa Telephone: +27 12 667 1046 Fax: +27 12 667 1029
Official Contact	Jade Rawlins Design Engineer Email: jade.r@southernimplants.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	External Hex Implant System
Common Name	Dental implant
Classification Name	Endosseous dental implant
Classification Regulation	21 CFR 872.3640, Class II
Product Code	DZE
Classification Panel	Dental Products Panel
Reviewing Branch	Dental Devices Branch

PREDICATE DEVICE INFORMATION

Primary predicate devices:
K163634, External Hex Implants, Southern Implants (Pty) Ltd.

Reference devices:
K212785, Blue Sky Bio Implant System, Blue Sky Bio, LLC.
K160119, NobelSpeedy Groovy, Nobel Biocare AB
K050406, NobelSpeedy Implants, Nobel Biocare AB
K222457, Provata Implant System, Southern Implants (Pty) Ltd.

INDICATIONS FOR USE STATEMENT

For Standard Length IBR36d Implant Range:
Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. When using Southern Implants' Standard Length IBR36D Implants with angulation of 36° a minimum of 4 implants must be used and splinted

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

For Extra Length IBR36d Implant Range:
Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Extra Length IBR36d Implants can be placed bicortically in cases of reduced bone density. Extra Length IBR36d Implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Extra Length IBR36d Implants 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.

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

For Extra Length IBR24d Implant Range:
Southern Implants' External Hex Implants are intended for surgical placement in the upper jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.

Southern Implants' Extra Length IBR24d Implant Range when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.

The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.

SUBJECT DEVICE DESCRIPTION

External Hex implants are fully-threaded, tapered, root-form dental implants with an external hexagonal abutment interface, and are threaded internally for attachment of mating multiple-unit abutments, cover screws, or healing abutments. The External Hex implants have a Co-Axis design with the prosthetic platform angled at 36° and 24° (inclined) from orthogonal to the long axis of the implant.

Additionally, the External Hex implants are provided in two configurations, regular surface and MSC surface implants. The regular surface implants are fully roughened excluding a machined collar at the coronal aspect of the implant. The MSC surface implants have an extended length of machined area at the coronal aspect of the implant, with the remaining implant length being roughened.

The implants subject to this submission are the External Hex IBR36d and IBR24d implant range. The reduced platform MSC-IBR24d implants are only provided as Co-Axis implants, in both the regular surface and MSC surface configuration. The reduced platform IBR36d implants are only provided as Co-Axis implants, in regular surface configuration. The IBR36d implants are available in two body configurations depending on the implant length.

The IBR36d implants of overall lengths 8.5 mm to 18 mm have a major body diameter of 4.20 mm tapering to 2.60 mm. The IBR36d implants of overall lengths 20 mm to 24 mm have a major body diameter of 4.20 mm tapering to 2.00 mm. Both the IBR24d and MSC-IBR24d implants of overall lengths 20 mm to 24 mm have a major body diameter 4.07 mm tapering to 2.60 mm. All of the subject device implants utilize the same prosthetic connection, previously cleared in K163634.

All External Hex implants are manufactured from unalloyed titanium (cold-worked, grade 4, UTS ≥ 900 MPa). The MSC-IBR24d implants have a smooth machined surface of length 3 mm extending parallel from the implant prosthetic platform for all implant lengths. The remainder of the implant is grit-blasted with aluminum oxide

particles to provide a surface roughness of 1-2 µm. The subject device implant material and surface are identical to those of the implants cleared in K163634.

The IBR36d and IBR24d External Hex implants are provided with a dedicated pre-mounted fixture mount of 36° and 24°respectively, similar to that provided with the other Co-Axis External Hex implants cleared in K163634.

All of the subject device implants utilize the same prosthetic connection, previously cleared in K163634 for the External Hex IBR24d and MSC-IBR24d implants. The External Hex implants are used in conjunction with the same abutments cleared for use with the External Hex IBR24d and MSC-IBR24d implants (implants cleared in K163634). These abutments are cleared in K053478, K070841, K093562, and K163634. The components that are compatible with the External Hex implants include Cover Screw, Healing Abutment, and Compact Conical Abutments. The Compact Conical Abutments are compatible with Temporary Titanium Abutment Cylinders, Gold Abutment Cylinders, and Passive Abutments.

The subject device Co-Axis implants are indicated for use with straight multiple-unit abutments with a 0° allowable restoration angle, only. This includes restricting straight abutments, that can be restored on a multi-unit abutment, that have an allowable restoration angle of up to 20° associated with them, so that they may only have a restoration angle of 0°. Thus, all the possible compatible abutments will have a 0° angulation and 0° allowable restoration angle.

All External Hex implants are provided sterile to the end-user in a single-unit package, and are for single-patient, single-use only.

PERFORMANCE DATA

Non-clinical data submitted, referenced, or relied upon to demonstrate substantial equivalence include: biocompatibility evaluations according to ISO 10993-1 (referenced from K163634); engineering analysis; dimensional analysis; sterilization validation according to ISO 11137-1, ISO 11137-2, ; bacterial endotoxin according to USP 39-NF 34; and sterile barrier shelf life (referenced from K222457).

Additionally, static and dynamic compression-bending according to ISO 14801 Dentistry – Implants – Dynamic fatigue test for endosseous dental implants was submitted. Fatigue testing for the subject device External Hex IBR36d and Extra Length IBR24d Implants was conducted on the representative worst-case construct for angulation and abutment/screw materials. For each subject device group, a total of twelve (12) samples were subjected to fatigue testing. The fatigue limit was determined to be where a total of three (3) samples endured 5 x 10^6 cycles with no failures. Results of mechanical testing performed in conformance to ISO 14801 confirmed that the strength of the subject device is sufficient for its intended use.

MR safety testing as per the recommendations of the FDA Guidance Document “Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment” (ASTM F2503, ASTM F2052, ASTM F2213, ASTM F2182, ASTM F2119) was performed on the previously cleared devices (referenced from K222457). The subject devices were compared to the predicate devices. The subject devices are not worst-case Southern Implants components in terms of material, size or shape and therefore the subject devices can be considered equally MR Safe as the predicate devices.

CLINICAL DATA

Standard length IBR36d:

A retrospective analysis of real-world clinical data was conducted as a means to support the clinical safety and performance of the Standard length IBR36d, with regards to the angulation of >30° and full scope of proposed indications, including longest implant body lengths, greatest allowed angulation, immediate and delayed loading protocols, splinting across multiple implants, and placement in both upper and lower jaws.

This clinical literature is presented as support for the subject implant’s angulation and dimensions as part of this submission. The dimensions of the implants identified in the literature are substantially equivalent or otherwise representative of the subject device (Ø4.2 and lengths of 8.5-18mm).

The indications for use for the subject device are in line with those reported on in the literature. These included the indication for use as prosthetic retention method in the rehabilitation of edentulism), suitability for both 1- and 2- stage surgical techniques (i.e., delayed or immediate loading) based on the user's evaluation, placement in the mandible and maxilla and the requirement for splinting.

The table below outlines the clinical literature submitted in the premarket notification submission for a determination of substantial equivalence in support of the standard length IBR36d implants. These articles provide information that demonstrates that standard length implants used clinically with an angulation range inclusive of 36° as part of a splinted approach are clinically safe and effective for their intended use.

This clinical data demonstrates that implants with a length of 7-18mm placed within an angulation range of 20-50° as part of a splinted approach present with similar success rates to standard implants. Survival rates and clinical indices were favorable in both maxillary and mandibular applications. Additionally, the data reported on immediate and delayed loading protocols, with favorable results observed in both indications. The standard length IBR36d implants are provided in lengths of 8-18mm and placed at angle of 36°. This is within the window of successful implants identified in the literature.

Extra length IBR36d:
A retrospective analysis of real-world clinical data was conducted as a means to support the clinical safety and performance of the extra length IBR36d, with regards to its full scope of proposed indications, with a specific focus on its longest implant body lengths, greatest allowed angulation, and use in the pterygoid region.

This clinical literature is presented as support for the subject implant's angulation and dimensions as part of this submission. The subject device dimensions (Ø4.2 and lengths of 20-24mm) are substantially equivalent for pterygoid placement.

The extra length IBR36d implants are intended to be used in the pterygoid region of the maxilla as shown in the clinical literature and as shown for the predicate devices in publicly available literature.

The table below outlines the clinical literature submitted in the premarket notification submission for a determination of substantial equivalence in support of the extra length IBR36d implants. These articles provide information to show that long implants used clinically in the pterygoid region are clinically safe and effective for their intended use.

Implants from 10 – 25 mm in length placed at angles 15°- 90° are used in the pterygoid region with a similar success rate to standard implants. The extra length IBR36d implants are provided in lengths of 20 mm – 24 mm and placed at an angle of 36°. This is within the window of the successful implants identified in the literature.

Conclusion:
The subject device implants with dimensions of Ø4.2mm and lengths of 8 mm – 24 mm do not raise new questions of safety and effectiveness compared to the predicate devices and the clinical literature available.

The standard length IBR36d implants are provided in lengths of 8.5 mm – 18 mm and placed at an angle of 36°. This is within the window of the successful implants identified in the literature. The angulation is smaller than the largest angulation reported where these greater angulations presented with favorable clinical outcomes. Additionally, the survival and success rates reported for angulated implants were consistent with those observed for implants placed under similar clinical conditions The standard length IBR36d implants present similar risks and benefits as angulated implants used in splinted restorations.

The extra length IBR36d implants are provided in lengths of 20 mm – 24 mm, placed at an angle in line with the protocol for pterygoid implant placement and feature a platform angle of 36°. This is within the window of the successful implants identified in the literature. Further, these implants are shorter than those placed in the zygoma which have less bone to implant contact and greater fulcrum force. Therefore, extra length IBR36d implants do not present greater risk than zygomatic implants or other alternative therapies.

Clinical Data for Standard Length IBR36d

Article	Ang. (°)	Length	Diameter	Arch	Loading	FU	Comments	Reference
1	30 – 45	8.5 – 18mm	NM	Both	Immediate	15 y	Survival rates of 97.51% at up to 17 years of function in the maxilla and 96.91% at up to 16 years of function in the mandible. In the maxilla, there was no difference observed between axial and tilted implants in all intervals considered. However, there was significantly less marginal bone loss observed around tilted implants of the mandible with respect to those placed axially, for most of the intervals considered.	E. L. Agliardi, A. Pozzi, D. Romeo, and M. Del Fabbro, "Clinical outcomes of full-arch immediate fixed prostheses supported by two axial and two tilted implants: A retrospective cohort study with 12–15 years of follow-up," Clinical Oral Implants Res, vol. 34, no. 4, pp. 351–366, Apr. 2023, doi: 10.1111/clr.14047.
2	30 – 45	13-15mm	4mm	Mand.	Immediate	3 y (42 m)	100% survival rate	M. Ayna, A. Gülses, and Y. Acil, "A comparative study on 7-year results of 'All-on-FourTM' immediate-function concept for completely edentulous mandibles: metal-ceramic vs. bar-retained superstructures," Odontology, vol. 106, no. 1, pp. 73–82, Mar. 2017, doi: 10.1007/s10266-017-0304-7.
3	45	11.5 -18 mm	3.5-5.0 mm	Both	Immediate	3 years	Survival rate of 98.7% at 36 months	C. A. Babbush, A. Kanawati, and J. Brokloff, "A New Approach to the All-on-Four Treatment Concept Using Narrow Platform NobelActive Implants," Journal of Oral Implantology, vol. 39, no. 3, pp. 314–325, Jun. 2013, doi: 10.1563/AAID-JOI-D-12-00223.
4	30 – 45	7 – 18mm	3.3-5mm	Max.	Immediate	5 y	Reported survival rates of 96.1% and 95.7% for tilted and axial implants, respectively. The marginal bone loss difference observed between the axial and tilted implant groups was not statistically significant.	M. Hopp, M. De Araújo Nobre, and P. Maló, "Comparison of marginal bone loss and implant success between axial and tilted implants in maxillary All-on-4 treatment concept rehabilitations after 5 years of follow-up," Clin Implant Dent Rel Res, vol. 19, no. 5, pp. 849–859, Oct. 2017, doi: 10.1111/cid.12526.
5	30 – 45	11 - 15mm	4mm	Mand.	Immediate	1 y	This study reported a high level of implant failures (10%), however; the same number of tilted implants	R. A. Landázuri-Del Barrio, J. Cosyn, W. N. De Paula, H. De Bruyn, and E.

							and straight implants failed suggesting that the angulation was not the principal reason for failure.	Marcantonio, "A prospective study on implants installed with flapless-guided surgery using the all-on-four concept in the mandible," Clinical Oral Implants Res, vol. 24, no. 4, pp. 428–433, Apr. 2013, doi: 10.1111/j.1600-0501.2011.02344.x
6	30 – 45	8.5 – 18 mm	4mm	Both	Immediate	5 y	Survival rate of 96.6% after 5 years. Reported a high level of mechanical complications which were attributed to the higher than normal incidence of heavy bruxer patients and had no negative impact on marginal bone loss or implant survival.	A. Lopes, P. Maló, M. De Araújo Nobre, and E. Sanchez-Fernández, "The NobelGuide® All-on-4® Treatment Concept for Rehabilitation of Edentulous Jaws: A Prospective Report on Medium- and Long-Term Outcomes," Clin Implant Dent Rel Res, vol. 17, no. S2, Oct. 2015, doi: 10.1111/cid.12260.
7	30 – 45	8.5 – 18mm	4mm	Both	Immediate	7 y	Reported a survival rate of 94.5% after 7 years.	A. Lopes, P. Maló, M. De Araújo Nobre, E. Sánchez-Fernández, and I. Gravito, "The NobelGuide All-on-4 Treatment Concept for Rehabilitation of Edentulous Jaws: A Retrospective Report on the 7-Years Clinical and 5-Years Radiographic Outcomes," Clin Implant Dent Rel Res, vol. 19, no. 2, pp. 233–244, Apr. 2017, doi: 10.1111/cid.12456.
8	30 – 45	8.5 – 18mm	4mm	Mand.	Immediate	10 y	The implant survival rate at 10 years was 94.8%. This survival rate accounts for both the axial and tilted implants; however, less than 50% of the implants that failed were tilted.	P. Malo, M. De Araújo Nobre, A. Lopes, S. M. Moss, and G. J. Molina, "A longitudinal study of the survival of All-on-4 implants in the mandible with up to 10 years of follow-up," The Journal of the American Dental Association, vol. 142, no. 3, pp. 310–320, Mar. 2011, doi: 10.14219/jada.archive.2011.0170.
9	≤45	13 – 18mm	4mm	Max.	Immediate	10 y	Survival rate of 98.1% for tilted implants at 3 years. A favorable level of bone loss was observed for tilted implants based on the Albrektsson criteria.	P. Maló, M. de A. Nobre, and A. Lopes, "Immediate loading of 'All-on-4' maxillary prostheses using trans-

								sinus tilted implants without sinus bone grafting: a retrospective study reporting the 3-year outcome," Eur J Oral Implantol, vol. 6, no. 3, pp. 219–226, 2013.
10	30 – 45	7 – 18mm	3.3-5mm	Max.	Immediate	13 y	Cumulative survival rate of 93.9% and favourable levels of MBL.	P. Maló, M. De Araújo Nobre, A. Lopes, A. Ferro, and M. Nunes, "The All-on-4 concept for full-arch rehabilitation of the edentulous maxillae: A longitudinal study with 5-13 years of follow-up," Clin Implant Dent Rel Res, vol. 21, no. 4, pp. 538–549, Aug. 2019, doi: 10.1111/cid.12771.
11	≈45	8.5-18mm	3.75mm	Max.	Immediate	18 y	Survival rate of 93% after 18 years. There was an increased density of failures observed following the 10 year follow-up which was partially explained by the advancing age of the population and the associated decrease in oral health practices and overall well-being. However, the observed survival rate of 93% at 18 years is higher than the acceptable level of survival of titanium implants proposed by Albrektsson of 91% at 15 years.	P. Maló, M. De Araújo Nobre, A. Lopes, A. Ferro, and J. Botto, "The All-on-4 treatment concept for the rehabilitation of the completely edentulous mandible: A longitudinal study with 10 to 18 years of follow-up," Clin Implant Dent Rel Res, vol. 21, no. 4, pp. 565–577, Aug. 2019, doi: 10.1111/cid.12769.
12	45	NM	NM	Both	Immediate and delayed	13 m	100% survival rate for tilted implants. The marginal bone loss difference observed between the axial and tilted implant groups was not statistically significant.	H. Najafi, H. Siadat, S. Akbari, and A. Rokn, "Effects of Immediate and Delayed Loading on the Outcomes of All-on-4 Treatment: A Prospective Study," Journal of Dentistry (Tehran), vol. 13, no. 6, pp. 415–422.
13	20 – 40	10-15mm	3.5-4.3mm	Mand.	Immediate	3 y (42 m)	No statistically significant difference was observed in marginal bone resorption or survival rates of the axial and tilted implant.	G. Sannino and A. Barlattani, "Straight Versus Angulated Abutments on Tilted Implants in Immediate Fixed Rehabilitation of the Edentulous Mandible: A 3-Year Retrospective Comparative Study," Int J Prosthodont, vol. 29, no. 3, pp. 219–226, May 2016, doi: 10.11607/ijp.4448.

14	≤45	>10	NM	Both	Immediate	3 y (42 m)	Survival rate of 100%. The authors observed a yearly bone loss greater than the accepted level (0.2mm) in both groups. This was justified by the inclusion of patients with unfavourable or chronic conditions that are known to affect the clinical outcome and survival of dental implants.	Á. L. Szabó et al., "Distally Tilted Implants According to the All-on-Four® Treatment Concept for the Rehabilitation of Complete Edentulism: A 3.5-Year Retrospective Radiographic Study of Clinical Outcomes and Marginal Bone Level Changes," Dentistry Journal, vol. 10, no. 5, p. 82, May 2022, doi: 10.3390/dj10050082.

Clinical Data for Extra Length IBR36d

Article	**Diameter**	**Length**	**Angle**	**Comment**	**Reference**
1	3.75 - 4.2mm	18 - 25mm	25-45°	As part of the conclusion, it was stated that the use of a "[p]terygoid implant provides a reasonable alternative to 3D maxillary reconstruction, sinus lifts, and bone augmentation technique. Many authors have reported success rates of pterygoid implants ranging from 90% to 100% after follow-up period ranging from 1 to 12 years with minimal complications. Avoidance of a prosthetic distal cantilever with good stability fit for immediate loading is possible with this technique."	P. V. R. Nag, P. Sarika, T. Bhagwatkar, and V. Dhara, "Pterygoid implant: Option for rehabilitation of the atrophic posterior maxilla," International Journal of Contemporary Dental and Medical Reviews, vol. 2019.
2	3.75 -4.0mm where not all diameters	10 – 22mm	35-55°	Thirteen articles were included, reporting a total of 1053 pterygoid implants in 676 patients. The weighted average success of pterygoid implants was 90.7%; bone loss evaluated radiographically ranged between 0 and 4.5 mm. No additional complications compared with conventional implants were	E. Candel, D. Peñarrocha, and M. Peñarrocha, "Rehabilitation of the Atrophic Posterior Maxilla With Pterygoid Implants: A Review," Journal of Oral Implantology,

	were identified			found, and patient satisfaction level with the prosthesis was high. Pterygoid implants have high success rates, similar bone loss levels to those of conventional implants, minimal complications and good acceptance by patients, being therefore an alternative to treat patients with atrophic posterior maxilla.	vol. 38, no. S1, pp. 461–466, Oct. 2012, doi: 10.1563/AAID-JOI-D-10-00200.
3	3.75 – 4.2mm	18-25mm	25-45°	This retrospective study evaluated implants of varying lengths used in the TTPHIL pterygoid implant surgery protocol. After 2 years of follow up, 121/125 of the implants were considered successful. Four implants failed within 2 months of placement and were accompanied by patient's complaints on pain, prosthetic mobility, bleeding or discomfort. The failures were confirmed by failed clinical mobility testing. Overall, this study reported a survival rate of 96.8% at 2 years and bone loss of 0.25 and 0.28mm at 1 and 2 years, respectively. 1 patient had ceramic chipping.	V. P. R. Nag et al., "Minimally Invasive Reconstruction of Atrophic Maxilla Using Novel TTPHIL Technique - A Retrospective Evaluation of Pterygoid Implants and Prosthesis Success in 75 Patients," Dent Adv Res, vol. 7, no. 1, Jan. 2022, doi: 10.29011/2574-7347.100086.
4	Stated as considered but not specified in the publication	13 – 20mm	15 - 90°	A total of 634 patients received 1.893 pterygoid implants, with a mean implant survival rate of 94.87%. The mean prevalence of implant failure was 0.056 with a 95% CI of 0.04 - 0.077. This study demonstrates that pterygoid implants can be successfully used in patients with atrophic posterior maxilla	R. Z. Araujo, J. F. Santiago Júnior, C. L. Cardoso, A. F. Benites Condezo, R. Moreira Júnior, and M. M. Curi, "Clinical outcomes of pterygoid implants: Systematic review and meta-analysis," J Craniomaxillofac Surg, vol. 47, no. 4, pp. 651–660, Apr. 2019, doi: 10.1016/j.jcms.2019.01.030.
5	3.75 – 4.0mm	18-20mm	15-60°	This retrospective study reported a survival rate of 93.9% and mean bone loss of 1.21mm after 3 years of loading.	M. M. Curi, C. L. Cardoso, and K. D. C. B. Ribeiro, "Retrospective Study of Pterygoid Implants in the Atrophic Posterior Maxilla: Implant and Prosthesis Survival Rates Up to 3 Years," Int J Oral Maxillofac Implants, vol. 30, no. 2, pp. 378–383, Mar. 2015, doi: 10.11607/jomi.3665.

EQUIVALENCE TO MARKETED DEVICE

Southern Implants (Pty) Ltd submits the information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, the subject device is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

K163634, External Hex Implants, Southern Implants (Pty) Ltd.
K160119, NobelSpeedy Groovy, Nobel Biocare AB
K212785, Blue Sky Bio Implant System, Blue Sky Bio, LLC.
K050406, NobelSpeedy Implants, Nobel Biocare AB

The primary predicate device for the subject device Standard Length IBR36d implants design is K163634. The reference device isK050406.

The primary predicate device for the subject device Extra Length IBR36d implants design is K163634. The reference device is K212785.

The primary predicate device for the subject device Extra Length IBR24d implants is K163634. The reference device is K160119.

A comparison of the technological characteristics of the subject devices and the primary predicate devices is provided in the following tables.

Comparison	Subject Device	Primary Predicate Device	Reference Device	Reference Device
	Standard Length IBR36d Implant Range **Southern Implants (Pty) Ltd**	**K163634** **External Hex Implants** **Southern Implants (Pty) Ltd**	**K212785** **Blue Sky Bio Implant System** **Blue Sky Bio, LLC**	**K050406** **NOBELSPEEDY Implants** **Nobel Biocare USA, LLC**
Indications for Use Statement	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. When using Southern Implants' Standard Length IBR36D Implants with angulation of 36° a minimum of 4 implants must be used and splinted. The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.	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 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.	NobelSpeedy implants are root-form endosseous implants intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient esthetics and chewing function. Nobel Biocare's NobelSpeedy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. NobelSpeedy implants may be placed immediately and put into immediate function providing that initial stability requirements detailed in the surgical manual are satisfied. NobelSpeedy implants are indicated for use in soft bone or whenever immediate or early loading is applied. The NobelSpeedy implants incorporate a groove on the implant thread and are11refered over models without the groove in these soft bone indications because bone forms more rapidly in the groove than on other parts of the implant resulting in increased stability when compared to non-groove implants. In addition, the NobelSpeedy implants are preferred in these soft bone indications because bone formation on the TiUnite® surface is more rapid and greater than on machined surface implants resulting in better maintenance of initial implant stability, faster and stronger osseointegration, and higher success rates. NobelSpeedy implants may be tilted up to 45°. When used with angulations between 30° and 45° a minimum of 4 implants must be used and splinted.
Product Code	DZE	DZE	DZE	DZE

Intended Use	Functional and esthetic rehabilitation of the edentulous mandible and maxilla.	Functional and esthetic rehabilitation of the edentulous mandible and maxilla.	Functional and esthetic rehabilitation of the edentulous mandible and maxilla.	Functional and esthetic rehabilitation of the edentulous mandible and maxilla.
Reason for Predicate/Reference	Not applicable	Implant Length Implant Design External Connection and Prosthetic Diameter Machined Collar Material and Surface Sterility and Usage	Implant Design Implant Diameter Platform Angle	Implant Angulation Indications for use restriction of 4 implants to be used and splinted.
Item Code	IBR36d	IBR24d; MSC-IBR24d	Not provided	Not provided
Implant Design	Fully threaded tapered root-form dental implants	Fully threaded tapered root-form dental implants	One-piece implant/abutment	Tapered apex with bone cutting flutes
Implant Diameter	4.20 mm	4.07 mm	3.0, 3.25, 3.5, 3.7 4.3 mm	Not provided
Implant Length	8.5, 10, 11.5, 13, 15, 18 mm	8.5, 10, 11.5, 13, 15, 18 mm	10, 11.5, 13, 16, 18, 20 mm	7, 8.5, 10, 11.5, 13, 15, 18 mm
Platform Angle, Relative to orthogonal to implant long axis	36° (inclined)	24° (inclined)	Straight, 17°, 30°, 45° (inclined) (45° in pterygoid placement only)	NobelSpeedy implants may be tilted up to 45o.
Implant Prosthetic Diameter	3.43 mm	3.43 mm	Not provided	Not provided
Machined Collar	Regular implants: 0.6 mm	Regular implants: 0.6 mm MSC implants: 3 mm	Not provided	Not provided
Implant Interface	External Hex	External Hex	One Piece	External Hex
Implant Material	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Ti-6Al-4V titanium alloy	CP Titanium
Implant Endosseous Surface	Grit-blasted	Grit-blasted	Grit blasted and acid etched	TiUnite
Sterility	Provided sterile	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

Comparison	**Subject Device**	**Primary Predicate Device**	**Reference Device**
	Extra Length IBR36d Implant Range **Southern Implants (Pty) Ltd**	**K163634** **External Hex Implant System** **Southern Implants (Pty) Ltd**	**K212785** **Blue Sky Bio Implant System** **Blue Sky Bio, LLC**

Indications for Use Statement	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. Extra Length IBR36d Implants can be placed bicortically in cases of reduced bone density. Extra Length IBR36d Implants are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. Extra Length IBR36d Implants 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. The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.	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.
Product Code	DZE	DZE	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.	Functional and esthetic rehabilitation of the edentulous maxilla.
Reason for Predicate/Reference	Not applicable	Implant Design External Connection and Prosthetic Diameter Machined Collar Material and Surface Sterility and Usage	Implant Design Implant Length Implant Diameter Platform Angle
Item Code	IBR36d-2X	IBR24d; MSC-IBR24d	Not Provided
Implant Design	Fully threaded tapered root-form dental implants	Fully threaded tapered root-form dental implants	Threaded root-form implant to be used with mating abutments
Implant Diameter	4.20 mm	4.07 mm	3.7, 4.3, 5.0 mm
Implant Length	20, 22, 24 mm	8.5, 10, 11.5, 13, 15, 18 mm	20, 22.5, 25 mm
Platform Angle, Relative to orthogonal to implant long axis	36° (inclined)	24° (inclined)	Straight, 12°, 17°, 24°, 30°, 45° (inclined) (45° in pterygoid placement only)
Implant Prosthetic Diameter	3.43 mm	3.43 mm	Not provided
Machined Collar	Regular implants: 0.6 mm	Regular implants: 0.6 mm MSC implants: 3 mm	Not provided
Implant Interface	External Hex	External Hex	Internal hex with 12° taper Internal hex with 45° bevel

Implant Material	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Ti-6Al-4V titanium alloy
Implant Endosseous Surface	Grit-blasted	Grit-blasted	Grit blasted and acid etched
How Provided			
Sterility	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

Comparison	**Subject Device** **Extra Length IBR24d Implant Range** **Southern Implants (Pty) Ltd**	**Primary Predicate Device** **K163634** **External Hex Implant System** **Southern Implants (Pty) Ltd**	**Reference Device** **K160119** **NobelSpeedy® Groovy** **Nobel Biocare LLC**
Indications for Use Statement	Southern Implants' External Hex Implants are intended for surgical placement in the upper jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved. Southern Implants' Extra Length IBR24d Implants allow also for bi-cortical anchorage in cases of reduced bone density. Southern Implants' Extra Length IBR24d Implant Range when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants. The angled Co-Axis External Hex Implants are intended to be used with straight multiple-unit abutments (Compact Conical abutments) only with no additional angulation allowable on the restoration.	Southern Implants' External Hex Implants are intended for surgical placement in the upper or lower jaw to provide a means for prosthetic attachment of crowns, bridges or overdentures utilizing delayed or immediate loading. Southern Implants' External Hex Implants are intended for immediate function when good primary stability with appropriate occlusal loading is achieved.	NobelSpeedy® Groovy implants are endosseous implants intended to be surgically placed in the upper or lower jaw bone for anchoring or supporting tooth replacements to restore patient esthetics and chewing function. NobelSpeedy® Groovy implants are indicated for single or multiple unit restorations in splinted or non-splinted applications. This can be achieved by a 2- stage or 1-stage surgical technique in combination with immediate, early or delayed loading protocols, recognizing sufficient primary stability and appropriate occlusal loading for the selected technique. Implants allow also for bi-cortical anchorage in cases of reduced bone density. NobelSpeedy® Groovy implants 20, 22, 25 mm when placed in the maxilla are only indicated for multiple unit restorations in splinted applications that utilize at least two implants.
Product Code	DZE	DZE	DZE
Intended Use	Functional and esthetic rehabilitation of the edentulous mandible and maxilla.	Functional and esthetic rehabilitation of the edentulous mandible and maxilla.	Functional and esthetic rehabilitation of the edentulous mandible and maxilla.
Reason for Predicate/Reference	Not applicable	Implant Design External Connection and Prosthetic Diameter	Implant Length Implant Design

		Implant Diameter Platform Angle Machined Collar Material and Surface Sterility and Usage	
Item Code	IBR24d; MSC-IBR24d	IBR24d; MSC-IBR24d	Not provided
Implant Design	Fully threaded tapered root-form dental implants	Fully threaded tapered root-form dental implants	Tapered apex with bone cutting flutes, to be used with mating abutments
Implant Diameter	4.07 mm	4.07 mm	4.0 mm
Implant Length	20, 22, 24 mm	6, 8.5, 10, 11.5, 13, 15, 18 mm	20, 22, 25 mm
Platform Angle, Relative to orthogonal to implant long axis	24° (inclined)	24° (inclined)	0° (straight)
Implant Prosthetic Diameter	3.43 mm	3.43 mm	Not provided
Machined Collar	Regular implants: 0.6 mm MSC implants: 3 mm	Regular implants: 0.6 mm MSC implants: 3 mm	Not provided
Implant Interface	External Hex	External Hex	External Hex
Implant Material	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	Unalloyed titanium (ASTM F67) Grade 4, and UTS ≥ 900MPa (cold-worked)	CP Titanium
Implant Endosseous Surface	Grit-blasted	Grit-blasted	TiUnite
How Provided			
Sterility	Provided sterile	Provided sterile	Provided sterile
Sterilization	Gamma irradiation	Gamma irradiation	Gamma irradiation
Usage	Single-patient, single-use	Single-patient, single-use	Single-patient, single-use

Subject device Standard Length IBR36d implants
The primary predicate device K163634 is for substantial equivalence of the subject device Standard Length IBR36d implant designs. The subject device implants have a similar indication for use, external hex connection, and lengths as implants cleared in K163634, specifically the IBR24d and MSC-IBR24d implants. The primary predicate device K163634 is also for substantial equivalence of the subject device implant material, machined collar length, endosseous surface, usage, sterility status, sterilization method and packaging shelf life.

The reference device K050406 is for substantial equivalence of the subject device implant platform angle and intended use restriction, indicating that for implants with an angulation of 36° a minimum of 4 implants must be used and splinted. Labeling mitigations were used to address differences in surgical protocol and technological characteristics as compared to predicate devices, to ensure safe and effective use of the subject device.

Subject device Extra Length IBR36d implants
The reference device K212785 is for substantial equivalence of the subject device Extra Length IBR36d implant designs. The reference device K212785 is for substantial equivalence of the subject device implant platform angle and lengths. Although differences in platform angle and lengths exist between the subject device and reference device, the reference device platform angles (17°, 30° and 45°) and implant lengths (20, 22.5 and 25 mm) encompasses the platform angle (36°) and implant lengths (20, 22 and 24 mm) of the subject device, as such the subject device does not represent a worst-case scenario in comparison to the reference device. The primary predicate device K163634 is used for substantial equivalence of the subject device external hex connection, implant material, machined collar length, endosseous surface, usage, sterility status, sterilization method, packaging shelf life, and indications for use statement, with a restriction limiting the use of these implants to surgical installation in the pterygoid region only, as per the reference device K212785. Labeling mitigations such as were used to address differences in surgical protocol and technological characteristics as compared to predicate devices, to ensure safe and effective use of the subject device.

Subject device Extra Length IBR24d implants
The primary predicate device K163634 is for substantial equivalence of the subject device Extra Length IBR24d implant designs. The subject device implants have a similar indication for use, identical external hex connection, platform angle machined collar, implant material, endosseous surface, usage, sterility status, sterilization method and packaging as implants in K163634, specifically the IBR24d and MSC-IBR24d implants.
The indications for use of the subject device implants in long lengths (i.e., 20, 22 and 24 mm) is limited to multiple unit restorations in splinted applications that utilize at least two implants, similar to the reference device K160119. Labeling mitigations were used to address differences in surgical protocol and technological characteristics as compared to predicate devices, to ensure safe and effective use of the subject device. The reference device K160119 is for the substantial equivalence of the subject device implant lengths (i.e., length 20, 22 and 24mm).

The subject device implants incorporate the same materials and encompass similar ranges of dimensions as the reference devices cleared in K163634, K212785, K160119, and K050406. The surface treatment applied to the endosseous threads of the subject device implants is identical to that cleared in K163634. All subject device components are for single-patient, single-use, and are provided sterile (the same as the reference devices cleared in K163634, K212785, K160119, and K050406).

Substantial equivalence of the subject device components in terms of biocompatibility is supported by the fact that materials are identical in formulation, processing, component interactions, and storage conditions to the predicate devices in K163634.

In support of substantial equivalence in terms of mechanical performance, dynamic compression-bending testing according to ISO 14801 *Dentistry – Implants – Dynamic fatigue test for endosseous dental implants* was performed. Dynamic testing was performed on worst-case subject device constructs. The results from the testing demonstrated fatigue performance of the subject devices that exceeds its indication.

CONCLUSION

The subject device and the predicate devices have a significantly similar intended use, have similar technological characteristics, and are made of the same materials. The subject device and the predicate devices encompass the same range of physical dimensions, including diameter and length of the implants. The subject devices are packaged in similar materials and sterilized using similar methods to previously cleared devices.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.