February 2, 2026

Chengdu Besmile Medical Technology Co., Ltd.
Moushan Liu
Manager
No.9, Sec.2, Shengwucheng North Rd
Chengdu Tianfu International Bio-Town, Shuangliu District
Chengdu, Sichuan 610200
CHINA

Re: K252286
Trade/Device Name: BIORES Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: July 2, 2025
Received: January 12, 2026

Dear Moushan Liu:

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.

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: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252286

Device Name
BIORES Dental Implant System

Indications for Use *(Describe)*
BIORES Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.
Implants with a diameter of 3.7 mm are only suitable for anterior tooth 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.

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510(k) Summary

K252286

1.Submitter

Device Submitter: Chengdu Besmile Medical Technology Co., Ltd.
No.9, Sec.2, Shengwucheng North Rd., Chengdu Tianfu International Bio-Town, Shuangliu District, Chengdu, Sichuan 610200, P.R.China

Contact Person: Moushan Liu (Mr.)
Manager
Phone: +86-28-85317108
E-mail: xuetaohu@cdbesmile.com

2.Device

Trade Name of Device:	BIORES Dental Implant System
Regulation Number:	21 CFR 872.3640
Classification Name:	Endosseous dental implant, Endosseous dental implant abutment
Product Code:	DZE, NHA
Regulatory Class:	Class II
Review Panel:	Dental
Date prepared:	February 2, 2026

3.Predicate Device

3.1 Primary predicate device

K171027, Dentis Dental Implant System by Dentis Co., Ltd.

3.2 Reference Device

K211090, ZENEX Implant System by Izenimplant Co., Ltd.

K192347, ST Internal Implant System by Megagen Implant Co. Ltd

4.Device Description

BIORES Dental Implant System includes Implant, Abutment and Accessories. Abutment and Accessories are only compatible with our company's Implant to restore patients' chewing function.

Implant is made of Titanium Grade 4 material that complies with ASTM F67 and has a sandblasted and acid-etched surface. The implant is supplied sterile and is gamma sterilized. The sterilization is shelf life for 8 years. Implant is classified into Type I Implant and Type II Implant according to different thread designs. Type I Implant feature conical threaded structures, consisting of a top, neck, and body. The top of the implant is machined (0.4mm length), the neck has trapezoidal micro-threads, and the body has large threads in a reverse sawtooth pattern, with rotational cuts at the large thread locations. Type II Implant have a conical threaded design, consisting of a top, and body. The implant body has large threads, and the large thread area has rotational cuts.

Abutment and Accessories include bonding abutment(straight only), healing abutment, central screw, and cover screw, all made from Ti-6Al-4V ELI titanium alloy material compliant with ASTM F136, without any surface treatment. The bonding abutment is provided non-sterile and must be sterilized by the user using steam sterilization prior to use; the healing abutment, central screw, and cover screw are provided sterile, with a sterilization shelf life of 5 years.

5.Indication for use

BIORES Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient’s chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.

Implants with a diameter of 3.7 mm are only suitable for anterior tooth restoration.

6. Substantial Equivalence Comparison

Device Characteristic	Subject Device	Primary predicate device	Reference Device	Reference Device	Discussion
Device name	BIORES Dental Implant System	Dentis Dental Implant System	ZENEX Implant System	ST Internal Implant System	/
510(k) number	K252286	K171027	K211090	K192347	/
Manufacturer	Chengdu Besmile Medical Technology Co., Ltd.	Dentis Co., Ltd.	Izenimplant Co., Ltd.	MegaGen Implant Co., Ltd.	/
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA	Identical
Indication for use	BIORES Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary stability has been achieved and with appropriate occlusal loading.	The Dentis Dental Implant System is an endosseous dental implant that is indicated for surgical placement in the upper and lower jaw arches, to provide a root form means for single or multiple-units prosthetic appliance attachment to restore a patient's chewing function. Implants can be placed with a conventional two stage surgical process with an option for transmucosal healing or they can be placed in a single stage surgical process for immediate loading when good primary	ZENEX Implant System is indicated for use in partially or fully edentulous mandibles and maxillae, in support of single or multiple unit restorations including; cemented retained, screw retained, or overdenture restorations, and final or temporary abutment support for fixed bridgework. It is intended for delayed loading. Wide Fixture System is intended to be used in the	The ST Internal Implant System is intended to be surgically placed in the maxillary or mandibular arches for the purpose providing prosthetic support for dental restorations (Crown, bridges, and overdentures) in partially or fully edentulous individuals. It is used to restore a patient's chewing function. Smaller implants (less than 6.0 mm) are dedicated for immediate loading when	Similar

	Implants with a diameter of 3.7 mm are only suitable for anterior tooth restoration.	stability has been achieved and with appropriate occlusal loading.	molar region.	good primary stability is achieved and with appropriate occlusal loading. Larger implants are dedicated for the molar region and are indicated for delayed loading.	

6.1 Implant

Device Characteristic	Subject Device	Primary predicate device	Reference Device	Discussion
Device name	Implant	s-Clean Tapered Fixture	ST Internal Fixture	/
510(k) number	K252286	K171027	K192347	/
Material	Titanium Grade 4 (ASTM F67)	CP Titanium Gr.4 (ASTM F67)	CP Ti Grade 4(ASTM F67)	Identical
Design	Tapered Internal Hex	Tapered, SAVE, Straight, and SAVE II designs, each Internal Hex connected	Tapered body Internal Hex	Similar Comment 1
Diameter(mm)	Type I: Φ3.7×8.4, 10.4, 12.4, 14.4 Φ4.1×8.4, 10.4, 12.4, 14.4 Φ4.3×8.4, 10.4, 12.4, 14.4 Φ4.8×8.4, 10.4, 12.4, 14.4 Φ5.5×8.4, 10.4, 12.4	3.7, 4.1, 4.3, 4.8, 5.5, 6.0mm	3.7, 4.2, 4.6, 5.1, 6.0, 6.8mm	Similar Comment 12
Length/Retention length(mm)		7, 8, 9, 10, 12, 14mm	7.0, 8.5, 10, 11.5, 13, 15mm	Similar Comment 2

	Φ6.0×8.4, 10.4, 12.4 Type II: Φ3.7×8.4, 10.4, 12.4, 14.4 Φ4.1×8.4, 10.4, 12.4, 14.4 Φ4.3×8.4, 10.4, 12.4, 14.4 Φ4.8×8.4, 10.4, 12.4, 14.4 Φ5.5×8.4, 10.4, 12.4 Φ6.0×8.4, 10.4, 12.4			
Threaded length(mm)	Type I: Φ3.7×8.0, 10.0, 12.0, 14.0 Φ4.1×8.0, 10.0, 12.0, 14.0 Φ4.3×8.0, 10.0, 12.0, 14.0 Φ4.8×8.0, 10.0, 12.0, 14.0 Φ5.5×8.0, 10.0, 12.0 Φ6.0×8.0, 10.0, 12.0 Type II: Φ3.7×8.0, 10.0, 12.0, 14.0 Φ4.1×8.0, 10.0, 12.0, 14.0 Φ4.3×8.0, 10.0, 12.0, 14.0 Φ4.8×8.0, 10.0, 12.0, 14.0 Φ5.5×8.0, 10.0, 12.0 Φ6.0×8.0, 10.0, 12.0	6.6, 7.6, 8.6, 9.6, 11.6, 13.6mm	7.0, 8.5, 10, 11.5, 13, 15mm	Similar Comment 3
Thread type	Knife thread	Knife thread	Knife thread	Identical
Placement type	Bone level	Bone level	Bone level	Identical

Surface treatment	SLA	RBM	SLA	Different Comment 1
Delivery	Sterile	Sterile	Sterile	Identical
Sterilization method	Gamma irradiation	Gamma irradiation	Gamma sterilization	Identical
Shelf life	8 years	8 years	5 years	Identical
Discussion	1.Similarities The Subject Device and the Primary predicate device K171027 have the same characteristics, including indication for use, material, diameter, thread type, placement type, sterilization method, and shelf life. 2.Differences Similar Comment 1 The Primary predicate device design includes Tapered, SAVE, Straight, and SAVE II, with an internal hex connection type. The Subject Device design is Tapered, with an internal hex connection type, which falls within the design range of the Primary predicate device. Therefore, this difference does not affect substantial equivalence. Similar Comment 12 The diameter of the subject device is identical to that of the primary predicate device. The diameter of the subject device is similar to that of the reference device. The minimum diameter of the Subject Device is 3.7 mm, and the maximum diameter is 6.0 mm. The minimum diameter of the Reference Device is 3.7 mm, and the maximum diameter is 6.8 mm. The diameter of the Reference Device covers the entire range of the Subject Device.			

	Therefore, this difference does not affect substantial equivalence. Similar Comment 2 The maximum length of the Primary predicate device is 14.0 mm, and the maximum length of the Subject Device is 14.4 mm. To accommodate this difference, Reference Device K1923471 has been added, with a length that covers the entire range of Subject Device dimensions. Therefore, this difference does not affect substantial equivalence. Similar Comment 3 The threaded length of the Primary predicate device is up to 13.6 mm, while that of the Subject Device is up to 14.0 mm. To accommodate this difference, Reference Devic K192347 has been added, which covers the entire range of dimensions of the Subject Device. Therefore, this difference does not affect substantial equivalence. Different Comment 1 The surface treatment method for the Primary predicate device is RBM, while that for the Subject Device is SLA. To support this difference, Reference Device K192347 with surface treatment method SLA has been added. Therefore, this difference does not affect substantial equivalence.

6.2Bonding Abutment

Device Characteristic	Subject Device	Primary predicate device	Discussion
Device name	Bonding Abutment	s-Clean Sole Abutment	/

510(k) number	K252286	K171027	/
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (Grade 5)	Identical
Diameter	4.5, 5.5, 6.5mm	4.5, 4.8, 5.5, 6.0, 6.5mm	Similar Comment 4
Length	9.0, 9.5, 10.0, 10.5, 11.0, 11.5, 12.0, 12.5, 13.0, 13.5, 14.0, 15.0mm	12.5, 13.0, 13.5, 14,15, 16, 17mm	Similar Comment 5
Transmucosal height	1.0, 1.5, 2.0, 2.5, 3.5, 4.5, 5.5mm	1.0, 1.5, 2.0, 2.5, 3.5, 4.5, 5.5mm	Identical
Post height	5.5,7.0mm	5.5, 7.0mm	Identical
Retention type to implant body	Screw-retained	Screw-retained	Identical
Dental restoration retention type	Bonding	Bonding	Identical
Delivery	Non sterile	Non sterile	Identical
Sterilization method	Steam sterilization by user	Steam sterilization by user	Identical
Discussion	1.Similarities The Subject Device and the Primary predicate device K171027 have the same characteristics, including material, transmucosal height, post height, retention type to implant body, dental restoration retention type, delivery, and sterilization method. 2.Differences Similar Comment 4		

	The diameter of the Primary predicate device includes 4.5, 4.8, 5.5, 6.0, and 6.5mm, while the diameter of the Subject Device is 4.5, 5.5, and 6.5mm, which falls within the size range of the Primary predicate device. Therefore, this difference does not affect substantial equivalence. Similar Comment 5 The maximum length of the Primary predicate device is 15.0mm, and the maximum length of the Subject Device is 17.0mm, which is within the size range of the Primary predicate device. Therefore, this difference does not affect substantial equivalence.

6.3 Healing Abutment

Device Characteristic	Subject Device	Primary predicate device	Discussion
Device name	Healing Abutment	s-Clean Healing Abutment	/
510(k) number	K252286	K171027	/
Material	Ti-6Al-4V ELI (F136)	Pure Titanium (Grade 4)	Different Comment 2
Diameter	4.5, 5.5, 6.5mm	4.0, 4.5, 4.8, 5.0, 5.5, 6.0, 6.5, 7.0, 7.5mm	Similar Comment 6
Length	10.0, 10.5, 11.0, 11.5, 12.5, 13.5, 14.5mm	9.5, 10.0, 10.5, 11.0, 11.5, 12.0, 12.5, 13.0, 13.5, 14.0mm	Similar Comment 7
Transmucosal height	1.0, 1.5, 2.0, 2.5, 3.5, 4.5, 5.5mm	1.0, 1.5, 2.0, 2.5, 3.5, 4.5, 5.5mm	Identical

Delivery	Sterile	Sterile	Identical
Sterilization method	Gamma irradiation	Gamma Irradiation	Identical
Shelf life	5years	8 years	Different Comment 3
Discussion	1.Similarities The Subject Device and the Primary predicate device K171027 have the same characteristics, including indication for use, delivery and sterilization method. 2.Differences Different Comment 2 The material of the Subject Device complies with the ASTM F136 standard and has undergone biological testing in accordance with ISO 10993, with no associated biological risks. Besides, the material is a commonly fabrication materials for abutment with a long history of clinical use. Therefore, this difference does not affect substantial equivalence. Similar Comment 6 The diameter of the Primary predicate device is 4.0~7.5mm, while the diameter of the subject device is 4.5, 5.5, or 6.5mm, which falls within the size range of the Primary predicate device. Therefore, this difference does not affect substantial equivalence. Similar Comment 7 The length of the Subject Device is 14.5 mm, with a tolerance of ±0.2 mm, which is very close to the length of the Primary predicate device (14.0 mm). The two are essentially equivalent. Therefore, this difference does not affect substantial equivalence.		

	Different Comment 3 The performance indicators of the Subject Device shelf life met the requirements after real-time aging testing. Therefore, this difference does not affect substantial equivalence.

6.4 Central screw

Device Characteristic	Subject Device	Primary predicate device	Discussion
Device name	Central screw	Abutment screw	/
510(k) number	K252286	K171027	/
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (Grade 5)	Identical
Diameter	2.3mm	2.32mm	Similar Comment 8
Length	9.8mm	8.8, 9.2, 9.4, 9.8, 9.95, 10.5 mm	Similar Comment 9
Delivery	Sterile	Non sterile	Different Comment 4
Sterilization method	Gamma irradiation	Steam sterilization by user	Different Comment 5
Discussion	1.Similarities The Subject Device and Primary predicate device K171027 have the same characteristics, including indication for use and material. 2.Differences Similar Comment 8 The diameter of the Subject Device is 2.3 mm, with a tolerance of ±0.2 mm, which differs from the diameter of the Primary		

	predicate device by 0.02 mm, which is within the diameter range of the Subject Device. Therefore, this difference does not affect substantial equivalence. Similar Comment 9 The length of the Subject Device is within the dimensions of the Primary predicate device. Therefore, this difference does not affect substantive equivalence. Different Comment 4/Different Comment 5 The Subject Device is provided sterile after gamma irradiation, and according to ISO 11137-1 and ISO 11137-2, the VDmax25 method confirms that a dose of 25 kGy can achieve the sterility assurance level (10^{-6}). Therefore, this difference does not affect substantial equivalence.

6.5 Cover screw

Device Characteristic	Subject Device	Reference Device	Discussion
Device name	Cover screw	Cover screw	/
510(k) number	K252286	K211090	/
Manufacturer	Chengdu Besmile Medical Technology Co., Ltd.	Izenimplant Co., Ltd.	/
Material	Ti-6Al-4V ELI (ASTM F136)	Ti-6Al-4V ELI (ASTM F136)	Identical
Diameter	3.5mm	3.0 ~ 3.9mm	Similar Comment 10

Length	7.2mm	5 ~ 7.3mm	Similar Comment 11
Delivery	Sterile	Sterile	Identical
Sterilization method	Gamma irradiation	Gamma irradiation	Identical
Discussion	1.Similarities The Subject Device and the Reference Device K211090 have the same indication for use, material, delivery and sterilization method. 2.Differences Similar Comment 10/Similar Comment 11 The diameter and length of the Subject Device are both within the dimensions of the Primary predicate device. Therefore, this difference does not affect substantive equivalence.		

7.Performance Testing

The following performance data were provided in support of the substantial equivalence determination.

7.1 Biocompatibility testing

Conduct biocompatibility evaluation in accordance with ISO 10993-1 Medical devices -Biological evaluation - Part 1: Evaluation and testing in the context of risk management. Cytotoxicity testing was conducted according to ISO 10993 - 5.

7.2 Sterilization validation

Irradiation sterilization validation is performed in accordance with ISO 11137-1 and ISO 11137-2 standards, and the VDmax25 method is used to confirm that a dose of 25 kGy achieves the sterility assurance level (10^{-6}).

Validated according to ANSI/AAMI/ISO 17665-1, 17665-2, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling and ANSI/AAMI ST79:2017 & 2020, validation of steam sterilization showed that it could achieve a sterility assurance level (10^{-6}).

7.3 Shelf life

Through real-time aging, the 8-year shelf life of the Implant and the 5-year shelf life of the Abutment and Accessories meet safety and efficacy requirements.

7.4 Pyrogen and Endotoxin Test

Bacterial endotoxin testing (Limulus amebocyte lysate, LAL) was conducted according to ANSI/AAMI ST72 and the endotoxin testing will be conducted on every batch for the subject device with the testing limit of below 20 EU/mL in accordance with the USP 39 <85>.

7.5 Fatigue Testing

Fatigue testing was conducted on the worst-case scenario for the declared device in accordance with ISO 14801.

7.6 Surface cleanliness analysis

Scanning electron microscopy (SEM) and Energy dispersive X-ray spectroscopy (EDS) confirmed that the Subject Device surface was clean, with no chemical

residues or particles remaining.

7.7 MR Environment Condition

Non-Clinical worst-case MRI review was performed to evaluated the BIORES Dental Implant System devices in the MRI environment using scientific rationale and published literature (e.g., Terry O. Woods, Jana Delfino, & Sunder Rajan. (2019). Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices. Journal of Testing and Evaluation 49.2, 783795), based on the entire system including all variations and material composition. Rationale addressed parameters per the FDA guidance "Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment," including magnetically induced displacement force and torque.

7.8 Non-Clinical Performance Data (Bench)

Performance testing was conducted on the Subject Device according to the technical specification, and the test results meet the standard.

8.Conclusion

The subject device and the predicate devices have the similar intended use, have similar technological characteristics, and are made of similar materials.

The documentation submitted in this pre-market notification demonstrates that the Subject Device is substantially equivalent to the Primary predicate device.