December 14, 2022

QRS Medical Ltd.
Iman Khorshid
CEO
St. Toval
Ma'alot-Tarshiha, 2101001
ISRAEL

Re: K221910
Trade/Device Name: QRS Dental Implants System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: November 14, 2022
Received: November 18, 2022

Dear Iman Khorshid:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Andrew I. Steen -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)*
K221910

Device Name
QRS Dental Implants System

Indications for Use *(Describe)*
QRS Dental Implants Systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.
The implants (Ø3.3mm and one-piece) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

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

QRS Dental Implants System

Applicant Name: QRS MEDICAL Ltd.
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Israel
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Establishment Registration Number: 3022766614

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WA, 98226
Tel: (716) 775-0533

Date prepared: December 12, 2022

Trade Name: QRS Dental Implants System

Classification name: Endosseous Dental Implant

Common/usual name: Dental Implant

Primary Product Code: DZE, Secondary product code: NHA

Regulation No.: 872.3640

Class: II

Panel identification: Dental Devices Panel

Description of the device:

QRS Dental Implants are self-tapping, root-form, one piece or two piece screw (Red Class, Blue Class and Gold Class) type dental implants, indicated for use in surgical and restorative applications for placement in the upper or lower jaw to provide support for prosthetic devices such as artificial teeth, in order to restore the patient chewing function.

The QRS' dental implant is a two stage screw type device that can equally well be used as one stage, surgically placed in the upper or lower jaw to provide support for prosthetic devices in partially or completely edentulous patients. The QRS' two piece implant is to be used in combination with several different abutments and superstructures provided in order to aid in the prosthetic rehabilitation.

QRS dental implants (Red Class, Blue Class and Gold Class) are designed with a standard internal hexagon system and provided in 3.3, 3.75, 4.2, 5.0 and 6.0mm diameter for lengths of 8, 10, 11.5, 13 and 16mm.

QRS dental implant one-piece is provided in 3.3 and 3.5mm diameter for lengths of 10, 11.5, 13 and 16mm.

The QRS' two piece dental implants are to be used in combination with cover screws, healing caps, abutments, smart attachment and straight multi-unit abutment according to commonly used protocol in the dental implantation field.

The QRS Dental Implants are made of Ti6AL4V ELI complying with standard ASTM F 136-13 - Standard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant.
The implants are grit blasted and acid etched surface.

All QRS' abutments, cover screws, healing caps, Straight ball attachment, smart attachment and strait multi- unit abutments are made of Ti6Al4V ELI titanium alloy

complying with ASTM F 136-13: Wrought Titanium-6 Aluminum -4Vanadium ELI alloy for surgical implant applications and ISO 5832-3: 2016: Implants for surgery -- Metallic materials -- Part 3: Wrought titanium 6-aluminium 4-vanadium alloy.

Abutments (straight abutments, angulated abutments (15°, 25°), and anatomic angulated abutments (15°, 25°)) are intended to be used in conjunction with endosseous dental implants fixture to aid in prosthetic rehabilitation. The abutments are intended for long term use and are in contact with tissue.
The abutments are available straight or angulated, in different heights and diameters to accommodate the patient's specific needs. They are available in 0, 15 or 25 degrees angulation.
Straight Abutment SP Titanium Abutment is provided in height of 5, 7 and 9mm.
Standard shoulder abutment in heights of 1, 2, 3 and 4mm
Standard Wide Shoulder Abutment is provided in heights of 1, 2, 3 and 4mm
Standard 15° Abutment is provided in heights of 2, 3 and 4mm
Standard 25° Abutment is provided in heights of 2, 3 and 4mm
The healing caps are intended for use with the implant system to protect the inner configuration of the implant, maintain, stabilize and enable formation of the soft tissue during the healing process. Healing Caps are provided in 4.5 diameter in heights of 3, 4, 5, 6 and 7mm. Wide Healing Cap is provided in 6 diameter in heights 3, 4, 5 and 6mm.

Straight Ball attachment are designed to increase retention of (partial) overdentures, supported on implants. QRS titanium Ball Attachments provide firm retention and stabilization of the overdenture when used with tissue-supported implant-retained overdentures and are compatible with QRS internal hexagon connection implants.

Straight ball attachments are provided in heights of 2, 3, and 4mm

Smart Attachment - Locator abutments are designed for use with overdentures or partial dentures retained in whole or in part by dental implants in the mandible or

maxilla. They offer multiple levels of retention and low vertical profile. The self-aligning design enables patients to easily seat their dentures. Smart attachment are provided with heights of 1, 2, 3 and 4mm.

Straight Multi-unit abutment are indicated for multiple unit reconstructions when screw retained prosthetics is preferred. Multi-unit abutments allow either direct screw of the prosthesis into the multi-unit abutment or connection to a fixed overdenture bar. Multi-unit abutments are provided in heights of 2, 3, 4 and 5 mm.

Abutments, healing caps, straight ball attachment, smart attachments and straight multi-unit abutment are provided non-sterile to the user and have to be sterilized prior to use by moist heat

All the Abutments, healing caps, straight ball attachment, smart attachments and straight multi-unit are intended for single use only.
QRS Implants are especially designed for implantation in a wide range of bone types and bone augmentation procedures.
Each two piece implant is supplied with a cover screw, which is intended for use with the implant system to protect the inner configuration of the implant, maintain, stabilize and enable formation of the soft tissue during the healing process.
Maximum compatibility and accuracy can be achieved when using compatible QRS tools, drills, accessories and prosthetic parts manufactured by QRS.

Indications for Use:

QRS Dental Implants Systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.
The implants (Ø3.3mm and one-piece) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support

for prosthetic devices such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.

Testing Summary:

Dynamic fatigue testing according to ISO 14801 was conducted to determine the implants are strong enough for their intended use.

Surface analysis according to the FDA guidance document was done including SEM and XPS.

Sterilization validation according to ISO 11137-1 and 11137-2 was conducted on the implants.

Abutment steam sterilization validation was done according to ISO 17665-1 and ISO 17665-2.

Package integrity testing according to ASTM F1929-12 and accelerated aging according to ASTM F1980-07 was conducted.

Materials used in the product meet ASTM F136 ,

Biocompatibility was demonstrated by testing the cytotoxicity according to ISO 10993-5.

Skin Sensitization and Intracutaneous according to ISO 10993-10.

Endotoxin testing according to USP 161 was conducted.

Cleanliness of implants was tested according to ISO 19227.

MRI Environment: MRI conditional

"Non-clinical worst-case MRI review was performed to evaluate the metallic devices in the MRI environment using scientific rationale and published literature (i.e., Woods, Terry O., Jana G. Delfino, and Sunder Rajan."Assessment of Magnetically Induced Displacement Force and Torque on Metal Alloys Used in Medical Devices." Journal of Testing and Evaluation 49.2 (2019): 783-795), based on the entire system to include all variations (all compatible implant bodies, dental abutments, and fixation screws) and material compositions. The 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."

Primary Predicate Device:

Dental Implant System manufactured by MIS Implant Technologies Ltd. and cleared under K180282.

Reference Device:

T.A.G. Dental Implant System K143326

Alpha-Bio Tec Dental Implant System K063364

Substantial Equivalence:

Technological Characteristics

The QRS Dental Implants System have the same intended use and principles of operation as MIS Implants' Dental Implants cleared under 510(k) K180282 and have equivalent performance characteristics. The material used for the QRS Dental Implants System, as well as the manufacturing methods are the same as the predicate device.

QRS' Implants system include four types of implants (Red Class, Blue Class, Gold Class and one-piece) and the predicate device include three types of implants (Seven, M4, UNO).

The additional of implant (Gold Class) don't affect the intended use and indication for use since they are meant to be used the same way as the primary predicate device: the gold class implant is intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate.

The Indications for Use statement for the subject device is not identical to the predicate device; however, the differences do not alter the intended use of the device nor do they affect the safety and effectiveness of the device relative to the predicate.

Both the subject and predicate devices are intended to be surgically placed in the bone of the upper or lower jaw arches for anchoring or supporting tooth replacement to restore chewing function, in partially or fully edentulous patients.

Predicate and subject devices have the same intended use and similar indications, Subject and predicate devices all have the same internal hex connection and internal geometry per platform.

They have the same following diameters: 3.3, 3.75, 4.2, 5 and 6.0.

The length range of the predicate device is 8 -16 mm. They all undergo the same surface treatment that was cleared under K180282, with additional anodizing in the internal hex connection of the implants.

Although there are minor differences in threading, apex, body design and neck design, these differences are common in end osseous implants and do not raise different safety or efficacy questions. Fatigue testing per ISO 14801:2016 assessed the impact of these differences and demonstrates at least equivalent performance.

	QRS Dental Implants System from QRS MEDICAL Ltd.	MIS Dental Implant System from MIS Implant Technologies Ltd Ltd.	Alpha-Bio Tec Dental Implant System	T.A.G. Dental Implant System
510(k) number	K221910	K180282	K063364	K143326
Product Code	DZE, NHA	DZE, NHA	DZE, NHA	DZE, NHA
Indications for Use	QRS Dental Implants Systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. The implants (Ø3.3 mm and one-piece) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices	MIS dental implant systems are intended to be surgically placed in the bone of the upper or lower jaw arches to provide support for prosthetic devices, such as artificial teeth, in order to restore masticatory function. When a one-stage surgical procedure is applied, the implant may be immediately loaded when good primary stability is achieved and the occlusal load is appropriate. Narrow implants (Ø3.3mm & UNO) are indicated for use in surgical and restorative applications for placement only in the mandibular central, lateral incisor and maxillary lateral incisor regions of partially edentulous jaws, to provide support for prosthetic devices such as artificial	The Alpha-Bio Tec Dental implant System is indicated for use in surgical and restorative applications for placement in the bone of the upper or lower jaw to provide support for prosthetic devices, such as artificial teeth, in order to restore the patient's chewing function. Alpha-Bio Dental Implant System is indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	The T.A.G. Dental Implant System is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process. The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading. The TAG "Crestone" dental implant (Ø3.0-Ø3.5) system is intended to replace single or multiple teeth in the fully or partially edentulous mandibular or maxillary alveolar process .The implants are appropriate for immediate loading when good primary stability is achieved and with appropriate occlusal loading

	QRS Dental Implants System from QRS MEDICAL Ltd.	MIS Dental Implant System from MIS Implant Technologies Ltd Ltd.	Alpha-Bio Tec Dental Implant System	T.A.G. Dental Implant System
	such as artificial teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another.	teeth. Mandibular central and lateral incisors must be splinted if using two or more narrow implants adjacent to one another. The long MIS (18 & 20 mm) implants can be used in a tilted manner. MIS short implants are to be used only with straight abutments. M4 short implants are indicated for delayed loading only.		
Supplied Sterile	Yes	Yes	Yes	Yes
Re-use	No	No	No	No
Material of Implants	Ti-6Al-4V, ELI	Ti-6Al-4V, ELI	Ti-6Al-4V, ELI	Ti-6Al-4V, ELI
Implants Shape	Screw type	Screw type	Screw type	Screw type
Connection method	Screw	Screw	Screw	Screw
Implants Surface	Sand blasted and acid etched	Sand blasted and acid etched	Sand blasted and acid etched	Sand blasted and acid etched
One piece implant	Ø3.3- Ø3.5 length 10-16 mm	Ø3.0- Ø3.5 length 10-16 mm		Ø3.0- Ø3.5 length 10-16 mm
Implants Length	8, 10, 11.5, 13 and 16mm	8, 10, 11.5, 13, And 16 mm	8, 10, 11.5, 13 and 16 mm	6,8,10,11.5,13 and 16 mm
Implants Diameter	3.3, 3.75, 4.2, 5 and 6.0 mm	3.3, 3.75, 4.2, 5.0 and 6.0 mm	3.3, 3.7, 4.2, 5.0, and 6.0 mm	3.3, 3.75, 4.2, 5.0, and 6.0 mm

	QRS Dental Implants System from QRS MEDICAL Ltd.	MIS Dental Implant System from MIS Implant Technologies Ltd Ltd.	Alpha-Bio Tec Dental Implant System	T.A.G. Dental Implant System
Abutments	Straight, 15° and 25°	Straight 10°,15°,20° and 25°	- Straight, 15° and 25° and 35°	Straight, 15° and 25°
Material of abutments	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI	Titanium Alloy – Ti6Al4V ELI
Surface treatment of abutments	None	None	None	None
Types of abutments	Multi-unit abutments in heights of 2,3,4 and 5 mm	Multi-unit abutments in heights of 2,3,4 and 5 mm	Multi-unit Attachment in heights of 0.7, 1.6, 2.6, 3.6, 4.6 and 5.6 mm	Multi-unit abutments in heights of 1,2,3,4 and 5mm
	Straight Ball attachments in heights of 2,3, and 4mm	Ball attachments in heights of 2,3,4 and 5mm	Ball attachments heights of 0.5,2,3,4,5, and 6mm	Ball attachments in heights of 1,2,3,4and 5mm
	Healing Caps 4.5 diameter in heights of 3,4,5,6 and 7mm	Healing Cap 4.6 in 3,4,5,6, mm height	Standard Healing Abutment heights of 2,3,4,5,6 and 7mm	Healing Caps 4 diameter in heights of 2,3,4,5 and 6mm
	Wide Healing Cap 6 diameter in heights 3,4,5and 6mm	Healing cap 5.5 in 3,4,5 and 6mm height.	Wide healing 5,5.5,6 abutment in heights of 3 and 5mm	Wide Healing Cap 5.8 diameter in heights 2,3,4and 5mm
	Straight Abutment SP Titanium Abutment with height of 5,7 and 9mm	4.5mm Standard Titanium Abutment with heights of 10 mm	with height of 8.5mm and 12mm	Standard Titanium Abutment with height of 9mm
	Standard shoulder abutment in heights of 1,2,3 and 4mm	Standard shoulder abutment in heights of 1,2,3 and 4mm	TLASP1 height 1 TLASP2 height 2 TLASP3 height 3 TLASP4 height 4	Standard shoulder abutment in heights of 1,2,3 and 4mm
	Standard Wide Shoulder Abutment with heights of 1,2,3 and 4mm	Standard Wide shoulder abutment in heights of 1,2,3 and 4mm	TLA02 height of 2 mm TLA04 height of 4 mm	Standard Wide Shoulder Abutment with heights of 1,2,3 and 4mm
	Standard 15° Abutment with heights of 2,3 and 4mm	Standard 15° Abutment with heights of 2 and 3mm	Standard 15° Abutment with heights of 1 and 2mm	Standard 15° Abutment with heights of 1,2 and 3mm
	Standard 25° Abutment with heights of 2,3 and 4mm	Standard 25° Abutment with heights of 2 and 3mm	Standard 25° Abutment with heights of 1 and 2mm	Standard 25° Abutment with heights of 1,2 and 3mm
	Smart attachment with heights of 1,2,3 and 4mm	Lockit attachment System with heights of 1,2,3 and 4mm	ALPHALOC attachment with heights of 0.5,1,2,3,4 and 5mm	Equator attachment with heights of 1,2,3, and 4mm

Non-Clinical Performance Data

Fatigue test was performed according to ISO 14801 on the QRS' dental implants and showed equivalence to the predicate devices.

Clinical Performance Data

No clinical performance data is provided in this submission.

Summary

The comparison between the subject device and the predicate devices has shown that the indications for use, principles of operation, technological characteristics and materials were similar, and that the differences did not raise new safety and effectiveness issues. Furthermore, performance testing showed that the predicate device is at least equivalent to the predicates by means of performance.

Conclusions

The QRS's dental system has the same intended use, incorporate the same fundamental technology, and has similar indications for use as the predicate. Test data to verify the performance of the QRS's dental system has been provided including: dynamic fatigue, sterilization validation, shelf life, and the results of this testing, combined with the design and intended use comparison with the predicate device, support substantial equivalence.