April 1, 2020

DSI Dental Solutions Ltd
% Angela Blackwell
Senior Consultant
Blackwell Device Consulting
P.O. Box 718
Gresham, Oregon 97030-0172

Re: K200188
Trade/Device Name: DSI Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: January 20, 2020
Received: January 24, 2020

Dear Angela Blackwell:

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,

for

Srinivas Nandkumar, Ph.D.
Director
DHT1B: Division of Dental 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K200188

Device Name
DSI Dental Implant System

Indications for Use *(Describe)*

DSI Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth , in order to restore patients esthetics and chewing function. DSI implants are intended for single or multiple unit restorations on splinted or non-splinted applications. Premium Spiral implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.

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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510k Summary
April 1, 2020
DSI Dental Implant System

Name and address: DSI Dental Solutions Ltd
59 haAvoda St Light Industrial Zone
Ashdod Israel 7706300
Contact Person: Shlomi Krasner
Phone Number: +972 200 3265
Name of device: DSI Dental Implant System
Classification Name: Endosseous dental implants
CFR: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA

Device Description: DSI Dental Implant System is an internal hex implant system with one model of implant at this time, Premium Spiral is a slightly tapered spiral internal hex implant with micro-rings at the implant neck which comes in 3.5, 3.75, 4.2, 5.0, and 6.0 diameter. The implants come in lengths of 8, 10, 11.5, 13 and 16. The 6.0 diameter implant does not come in lengths of 13 or 16mm.

All implants and abutments are made of ASTM F136 Ti 6Al 4V ELI. The implants have a grit blasted and acid etched surface. Loc-in abutments are anodized. All types of abutments can be used with all implants.

Straight abutments, standard narrow abutments, anatomic angled abutments, straight shoulder abutments, and straight wide shoulder abutments are all screw-retained permanent abutments for single or multiple restorations. The system also includes abutment fixation screws. Straight abutments come in 7, 9, or 11mm lengths and shouldered straight abutments come 1, 2, 3, or 4mm in gingival height. Wide straight shoulder abutments come in gingival heights of 1, 2, or 3mm. Standard narrow abutments come in lengths of 7, 9, 11 mm. Straight wide abutments come in lengths of 9 or 11 mm. 15° anatomic angulated abutments come in gingival heights of 1, 2, or 3 mm. 25° anatomic angled abutments come in gingival heights of 1, 2, or 3mm.

Straight multi-unit abutments, Loc-in abutments, overdenture abutments, and ball attachments are permanent threaded abutments which are for multi-restorations only. Loc-in abutments come in collar heights of 0.5, 1, 2, 3, 4, 5, and 6 mm. Ball attachments come in gingival heights of 0.5, 1, 2, 3, 4, 5, or 6mm. Overdenture abutments come in gingival heights of 0.5, 1.5, or 2.5 mm. Overdenture abutments are used with removable dentures and partial dentures. Straight multi-units come in gingival heights of 1, 2, 3 or 4 mm. Multi-unit abutments are used for fixed restorations. Straight multi-unit mounted dentures can only be removed by the dentist, but dentures mounted on flat abutments, overdentures or ball attachments can be removed by the patient.

The UCLA is 4.5mm in diameter and is for making gold restorations which are taller than 4mm.

Healing caps (3.8, 4.5, 5.5, and 6.0 mm diameter) are temporary use abutments used during the healing phase which come in different gingival heights in order to account for tissue thickness differences. The 3.8mm diameter healing caps come in gingival heights of 3, 4, 5, 6 and 7 mm. The 4.5 and 5.5 mm diameter healing caps come in gingival heights of 2, 3, 4, 5, 6 and 7mm. The 6.3 mm diameter healing cap comes in gingival heights of 2, 3, 4, and 5 mm.

Indications for Use: DSI Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patients esthetics and chewing function. DSI implants are intended for single or multiple unit restorations on splinted or non-splinted applications. Premium Spiral implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.

Testing Summary: Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments and implants are strong enough for their intended use. Premium Spiral implants exhibited a run out limit about the same or higher than other implant systems. Surface analysis was done to show the surface treatment does not adversely change the cytotoxicity of the materials. All the materials are ones common in dental implant systems. Implants and abutments are made of titanium alloy which meets ASTM F136. Sterilization validation was conducted on the implants according to ISO 11137-1, ISO 11137-2, and ISO 11137-3. Abutment steam sterilization validation was done according to ISO 17665-1 and ISO 17665-2. Package integrity testing and accelerated aging were conducted. Endotoxin testing according to USP 161 was conducted.

Primary Predicate Device: SpiralTech Dental Implant System Esi Hex K170372
Reference Predicates: Cortex K090709 Ditron MPI K140728

Substantial Equivalence:
DSI Dental Implant System is substantially equivalent to SpiralTech Dental Implant System in indications for use, materials, design, and fatigue performance.

Implant System Comparison Table	DSI Dental Implant System Premium Spiral	SpiralTech Dental Implant System K170372 ESi Hex	Ditron MPI K140728
Diameter of Implants Premium Spiral	3.5, 3.75, 4.2, 5.0, 6.0	ESi Hex 3.3, 3.5, 4.3, 5.0, 6.0	3.3, 3.5, 3.75, 4.2, 5.0, 6.0
Implant Lengths	8, 10, 11.5, 13, 16 (6.0 mm diameter not in 13 or 16 length)	8, 10, 11, 13, 15	6 (4.2, 5 and 6 only), 8, 10, 11.5, 13, and 16
Surface Treatment	SLA	SLA or RBM	Unknown
Sterilization of Implants	Provided sterile by gamma irradiation	Provided sterile by gamma irradiation	Provided sterile by gamma irradiation

Sterilization of abutments	Provided non-sterile with instructions for user to sterilize them	Provided non-sterile with instructions for user to sterilize them	Provided non-sterile with instructions for user to sterilize them
Connection	Internal Hex	Internal Hex	Internal Hex
Spiral Implant Design	Premium Spiral	ESi Hex	MPI
ISO 14801 Fatigue Test	Run out limit is the same or higher than those of other implant systems	Run out limit is comparable to other implant systems.	Run out limit is comparable to other implant systems.
Indications for Use	DSI Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patients esthetics and chewing function. DSI implants are intended for single or multiple unit restorations on splinted or non-splinted applications. Premium Spiral implants are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants can also be used for loading after a conventional healing period.	The Spiraltech Dental Implants are endosseous implants intended to be surgically placed in the upper or lower jaw arches to provide support for prosthetic devices, such as an artificial tooth, in order to restore patient's esthetics and chewing function. Spiraltech implants are intended for single or multiple unit restorations on splinted or non-splinted applications. The implants ESi Dynamic and Ultimate are intended for immediate loading when good primary stability is achieved, and with appropriate occlusive loading. These implants [along with Premium and One Piece] can also be used for loading after a conventional healing period. Solo One Piece 3.0 and 3.3 implants, Ultimate (conical) 3.0 implants, and ESi (conical) 3.0 implants are intended to replace a lateral incisor in the maxilla and/or a central or lateral incisor in the mandible. Mandibular central and lateral incisors must be splinted if using two or more 3.0 and/or 3.3	Ditron's Dental Implants and Abutments are 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. • Two stage: MPI, ULT, API and CPI models • One stage: OPI model The 3.3 and 3.0 mm diameter models for One stage OPI, Two stage MPI, Two stage and API implants are intended only for the incisors and cuspids of the maxilla and mandible. They are also indicated for denture stabilization using multiple

		implants adjacent to one another.	implants. Two stage and One stage implants for temporary or longterm use: MPI, ULT, API, CPI, OPI are self-tapping titanium threaded screws indicated for long term intra bony applications. They permit immediate splint stability and long-term fixation of new or existing crown, bridge and prosthesis and protection of graft sites. MPI, ULT, API, CPI and OPI designs are indicated for immediate loading (except for MPI and API in 6mm length) when good primary stability is achieved and with appropriate occlusal loading. MPI, ULT, API, CPI and OPI are indicated for immediate loading (except for MPI and API in 6mm length) in single tooth restorations when good primary

			stability is achieved with appropriate occlusal loading.
Material	Ti6Al4V	Ti6Al4V	Ti6Al4V

	DSI Dental Implant System	**SpiralTech Dental Implant System K170372**	**Cortex Dental Implant System K090709**
Cover screw	Cover screw	Cover screw	
Multi-Unit Abutments*	Multi-unit abutments in heights of 1,2,3 and 4 mm Used for fixed restorations.	Multi-unit abutments in heights of 1,2,3 and 4 mm Used for fixed restorations.	
Ball attachments*	Ball attachments in heights of 2,3,4,5, and 6mm	Ball attachments in heights of 1,2,3,4,5, and 6mm	
Healing Caps 3.8 diameter	Healing Cap in 3,4,5,6,7 mm height	Healing Abutment in 2,3,4,5 and 6 mm height	Healing abutment 7mm height
Healing Caps 4.6 diameter	Healing cap in 2,3,4,5,6, and 7mm height	Healing Abutment in 2,3,4,5, and 6 mm height	Healing abutment 7mm height
Healing Caps 5.5 diameter	Healing cap in 2,3,4,5,6 and 7mm height	Healing Abutment in 2,3,4,5,and 6mm height	Healing abutment 7mm height
Healing Caps 6.3 diameter	Healing Caps in 2,3,4 and 5 mm height		Healing Abutments in 2,3, 4 and 5 mm height
Standard Titanium Abutment	4.5mm Standard Titanium Abutment with heights of 7,9, and 11 mm	4.5mm Standard Flat Titanium Straight Abutment with height of 5,7,9 and 11 mm	
Standard Narrow Abutment	3.8mm Standard narrow abutment with heights of 7,9 and 11 mm	3.8mm Narrow Flat Titanium Straight abutment with heights of 5, 7, 9, and 11mm	
Standard Wide Abutment	5.5mm Standard wide abutment with heights of 9 mm	5.5mm Wide Flat Titanium Straight abutment with heights of 5,7,9,and 11 mm	

Standard Shoulder Abutment	4.5mm Standard shoulder abutment in heights of 1,2,3 and 4mm	4.5mm Anatomic Titanium abutment in heights of 1,2,3 and 4mm	
Standard Wide Shoulder Abutment	5.4mm Standard Wide Shoulder Abutment with heights of 1,2,3 mm	5.5mm Wide Anatomic Abutment with heights of 1,2 ,and 3mm	
Standard 15° Abutment	Standard 15° Abutment with heights of 1,2,3 mm	15° Angulated Titanium Abutment with heights of 1,2,3 mm	
Standard 25° Abutment	Standard 25° Abutment with heights of 1,2,3 mm	25° Angulated Titanium Abutment with heights of 1,2, and 3mm	
Loc-In Abutments *	Flat abutment in heights of 1,2,3,4,5,and 6 mm	IPI abutment in heights of 1,2,3,4,5 and 6 mm	
Standard Overdenture Abutment*	Overdenture abutment in 0.5, 1.5, and 2.5 mm heights Used for removable restorations.		Clever click attachment with heights of 0,1,2,3,4,5 mm Used for removable restorations.
UCLA	Castable abutments in diameters 4.5mm		Castable abutments 4.5mm diameter

***These models of abutments are not for single crown use.**

Conclusion:

DSI Dental Implant System is substantially equivalent to SpiralTech Dental Implant System. They both have similar indications for use, are of the same material, and have internal hex connections. The language regarding small diameter implants in the predicate Indications for Use is not relevant to the subject Indications, as the smallest diameter of subject implants is outside of the predicate's specifically indicated range. The reference devices do not include any specific language in their Indications related to the components being compared to the subject system.

Performance testing demonstrates substantial equivalence to the identified predicate devices.

The abutments, healing caps, and angled abutments are offered in similar designs and heights. Any abutments not found in the predicate device system are found in the reference device system. The design and size differences between predicate or reference devices and the subject devices are only minor differences in geometry and size so given the use, materials and technology is the same they do not change the substantial equivalence.