September 23, 2021

Abracadabra Implants Ltd
Vladislav Dvoyris
VP Marketing and Clinical Education
12 Hacharoshet St.
Or-Yehuda 6037580
ISRAEL

Re: K202092
Trade/Device Name: ABC Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: August 23, 2021
Received: August 27, 2021

Dear Vladislav Dvoyris:

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 Andrew 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)*
K202092

Device Name
ABC Dental Implant System

Indications for Use *(Describe)*
The ABC 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. The ABC Dental Implant System is also indicated for immediate loading when good primary stability of the implants is achieved, and with appropriate occlusal loading.

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, September 18, 2021
ABC Dental Implant System – K202092

Name and address: Abracadabra Implants Ltd
12 Hacharoshet St
Or Yehuda, Israel, 6037580
Contact Person: Daniel Younisian
Phone Number: +972 52 600 8222
Name of device: ABC Dental Implant System
Classification Name: Endosseous dental implant
CFR: 21 CFR 872.3640
Primary Product Code: DZE
Secondary Product Code: NHA

Trade name information: The ABC Dental Implant System is intended to be marketed under the trade name "ABraCadabra Implants".

Primary Predicate Device: Alpha-Bio Tec® Dental Implant System (SPI DFI NEO) – K063364
Reference Devices: ARDS Dental Implants (Classic and Premium CIC) - K071803

Device Description: ABC Dental Implant System is an internal hex implant system with one model of implant at this time. ABC dental implant is a slightly tapered cylindrical internal hex implant with micro-rings at the implant neck, which comes in 3.3, 3.75, 4.2, 5.0, and 6.0 diameter. The implants come in lengths of 8, 10, 11.5, 13, and 16. The 5.0 and 6.0 diameter implants do not come in a length of 16mm.

All implants and abutments are made of ASTM F136 Ti 6Al 4V ELI. The implants have a grit blasted and acid etched surface. 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. Straight abutments come in 5, 7, 9, or 11mm lengths and shouldered straight abutments come 1, 2, 3, or 4mm in height. Wide straight shoulder abutments come in heights of 1, 2, or 3mm. Standard narrow abutments come in lengths of 5, 7, 9, 11 mm. Smooth straight wide abutments come in lengths of 5, 7, 9, and 11 mm and the grooved version comes only in 9mm. 15° anatomic angulated abutments come in heights of 1, 2, or 3 mm. 25° anatomic angled abutments come in heights of 1, 2, or 3mm.

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

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 heights of 3, 4, 5, 6 and 7 mm. The 4.5 and 5.5 mm diameter healing caps come in heights of 2, 3, 4, 5, 6 and 7mm. The 6.3 mm diameter healing cap comes in heights of 2, 3, 4, and 5 mm.

Indications for Use:
The ABC 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. The ABC Dental Implant System is also indicated for immediate loading when good primary stability of the implants is achieved, and with appropriate occlusal loading.

Substantial Equivalence:
ABC Dental Implant System is substantially equivalent to Alpha-Bio Tec Dental Implant System in indications for use, materials, design, and fatigue performance.

Characteristic	**ABC Dental Implants (Bolero)**	**Alpha-Bio Tec® Dental Implant System (SPI DFI NEO)**	**ARDS Dental Implants (Classic and Premium CIC)**
Intended Use/Indication	The ABC Dental Implants 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, to restore the patient's chewing function. The ABC Dental Implants System is also indicated for immediate loading when good primary stability is achieved and with appropriate occlusal loading	The Alpha-Bio 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, to restore the patient's chewing function. The Alpha-Bio Dental Implant System® is indicated also for immediate loading when good primary stability is achieved and with appropriate occlusal loading.	ARDS dental implants are indicated for use in surgical and restorative applications for placement in the bone of the upper and lower jaw to provide support for prosthetic devices to restore the patient's chewing function. ARDS dental implants are indicated for two-stage surgery.
Site/Bone type	**Bolero** is suitable for dense bone D1 / D2 and soft bone D3 / D4 in the upper or lower jaw.	**SPI** does not state a specific site or bone site indication. **DFI** is referred by the manufacturer as Suitable for all bone types, ideal for use in bone types D2 and D3. **NEO** is referred by the manufacturer as Suitable for all bone types D2, D3 and D4.	**Classic** will optimally be used for softer bone when bone compression around the implant can be done **Premium** recommended to be used also for harder and more condensed bones such as type D1 **CIC** is referred by the manufacturer as Suitable for all bone types, ideal for use in bone types D2 D3 and D4.
Population	Edentulous and partially dentate patients	Edentulous and partially dentate patients	Edentulous and partially dentate patients
Performance	Intended to provide support for prosthetic devices, such as artificial teeth, in order to	Intended to provide support for prosthetic devices, such as artificial teeth, in order to	Intended to provide support for prosthetic devices, such as artificial teeth, in order to

Characteristic	ABC Dental Implants (Bolero)	Alpha-Bio Tec® Dental Implant System (SPI DFI NEO)	ARDS Dental Implants (Classic and Premium CIC)
	restore the patients' chewing function.	restore the patients' chewing function.	restore the patients' chewing function.
Device Design	Screw-shaped Titanium dental implant - **Bolero** parallel	Screw-shaped Titanium dental implant **SPI** Conical **DFI** parallel **NEO** Conical	Screw-shaped Titanium dental implant **Classic** - Conical **Premium** - Parallel **CIC**- Conical
Placement Method	One and two-stage procedure.	One and two-stage procedure.	Two-stage procedure.
Material	Ti-6Al-4V Eli ASTM F136 (Grade 5)	Ti-6Al-4V Eli (Grade 5)	Ti-6Al-4V Eli (Grade 5)
Dimensions and tolerances Diameter (mm)	**Bolero** – 3.3, 3.75, 4.2, 5mm ±0.1mm	**SPI** – 3.3, 3.75, 4.2, 5, 6mm ±0.1mm **DFI**- 3.3, 3.75, 4.2, 5mm ±0.1mm **NEO**- 3.75, 4.2, 5.0mm ±0.1mm	**Classic** - 3.3, 3.75, 4.2, 5, 6mm ±0.1mm **Premium** -3.3, 3.75, 4.2, 5, 6mm ±0.1mm **CIC**- 3.5mm ±0.1mm
Dimensions and tolerances length (mm)	6, 8, 10, 11.5, 13, 16mm±0.1mm	6, 8, 10, 11.5, 13, 16mm±0.1mm	8, 10, 11.5, 13, 16mm±0.1mm
Anti-rotational features-internal external hexagonal, etc.	internal hexagonal	internal hexagonal	internal hexagonal
Device features	Self-tapping and self-condensing tapered titanium screw implant	Self-tapping and self-condensing tapered titanium screw implant with variable thread design	Self-tapping titanium screw implant with dual thread design
Flat axial surface features on the implant	None	None	None
Internal hex. threads(inch)	1#72	1#72	1#72
Abutment connection	Hexagon + screw	Screw or hexagon + screw	Screw or hexagon + screw
Surface treatment	Sandblasting, followed by cleaning by acid treatment	Sandblasting, followed by cleaning by acid treatment	Sandblasting, followed by cleaning by acid treatment
Packaging	Double vial	Vial and a Blister	Double vial
Implant Sterilization	Gamma Radiation	Gamma Radiation	Gamma Radiation
Components	The ABC Dental Implant System consists of one and two-stage endosseous form dental implants with an internal hexagonal connection; cover screw and healing caps; abutment systems and superstructures; surgical instruments (*).	The Alpha-Bio Dental Implant System® consists of one and two-stage endosseous form dental implants, with an internal hexagonal connection; cover screws and healing caps; abutment systems and Superstructures; surgical instruments (*).	The Alpha-Bio Dental Implant System® consists of one and two-stage endosseous form dental implants, with an internal hexagonal connection; cover screws and healing caps; abutment systems and Superstructures; surgical instruments (*).
Abutments [refer to abutment comparison in the rows below]	Straight & up to 25°	Straight & up to 25°	Straight & up to 25°

		ABC	Alpha Bio	ARDS Dental Implants
Abutment Type/Dimensions	Standard abutment	screw thread – 1#72 inch. Diameter: 3.8, 4.5, 5.5	screw thread – 1#72 inch. Diameter: 3.5, 4.5, 5.5 mm	screw thread – 1#72 inch. Diameter: Slim - 3.8mm Normal - 4.5mm, Wide - 5.5,6.3mm
	Standard abutment with shoulder	screw thread – 1#72 inch. Diameter:3.8, 4.5, 5.5mm. Shoulder height: 1, 2, 3, 4mm.	screw thread – 1#72 inch. Diameter: 4.5, 5.5mm Shoulder height: 1, 2,3,4mm.	screw thread – 1#72 inch. Diameter: normal - 4.5mm, wide - 5.5mm, Shoulder height 1-4mm
	15° Angular abutment	screw thread – 1#72 inch. Diameter: 4.5, mm.	screw thread – 1#72 inch. Diameter: 4.5, mm.	screw thread – 1#72 inch. diameter- ,normal- 4.5mm, wide- 5.5 mm
	25° Angular abutment	screw thread – 1#72 inch. Diameter: 4.5, mm.	screw thread – 1#72 inch. Diameter: 4.7mm.	screw thread – 1#72 inch. diameter- 4.7mm
	15° Angular abutment with shoulder	screw thread – 1#72 inch. Diameter: 4.5, mm. Shoulder height 1,2,3,4mm.	screw thread – 1#72 inch. Diameter: 4.7mm. Shoulder height 1,2,3mm.	screw thread – 1#72 inch. Diameter -4.5 mm, Shoulder height 1-2mm
	25° Angular abutment with shoulder	Connection: Internal hexagon - 2.43 mm diameter, screw thread – 1#72 inch. Diameter:4.5, mm. Shoulder height 1,2,3,4mm.	Connection: Internal hexagon - 2.43 mm diameter, screw thread – 1#72 inch. Diameter: 4.7mm. Shoulder height 1,2,3mm.	Connection: Internal hexagon - 2.43 mm diameter, screw thread – 1#72 inch. Diameter - 4.7 mm, Shoulder height 1-2mm
	Standard Healing Cap	4.6 mm in diameter L: 2-8mm	4.6 mm in diameter L: 2-7mm	4.5 mm in diameter L: 3,5mm
	Standard Healing Cap Narrow	3.8 mm in diameter L: 2-7mm	3.85 mm in diameter L: 3-5mm	3.8 mm in diameter L: 3,5mm
	Standard Healing Cap Wide	5.5 mm in diameter L: 2-7mm	5.5 mm in diameter 3,5mm	4.7 mm in diameter L: 3,5mm
	Standard Healing Cap Extra Wide	6.3 mm in diameter L: 2-5mm	6.3 mm in diameter L: 3,5mm	N/A

		ABC	Alpha Bio	ARDS Dental Implants
	Standard Ball Attachment	H: 1-7mm	L: 0.5-6mm	H: 1-5mm
	Standard Multi Unit	L: 1-4mm	L: 2.1	L: 1-5mm
Surface treatment		None	None	None

Non-Clinical Performance Testing: Dynamic fatigue testing according to ISO 14801 was conducted to determine the abutments and implants are strong enough for their intended use. ABC 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. Biocompatibility testing was performed on the implants and abutments, and both substrates were found not to have cytotoxic potential, according to the requirements of ISO 10993-5.
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. Abutment steam sterilization validation was done. Package integrity testing and accelerated aging were conducted. Endotoxin testing according to USP 161 was conducted.

Conclusion – Statement of Substantial Equivalence:

ABC Dental Implant System is substantially equivalent to Alpha-Bio Tec Dental Implant System. They both have the similar indications for use, are of the same material, and have internal hexagon connections.

Performance testing demonstrates that the subject device exhibits equivalent performance to the predicate device. They use the same type of technology for their surface treatments and manufacturing. The abutments, healing caps, and angled abutments are offered in similar designs and heights. Performance testing showed that the subject device performs as well as the predicate device. Therefore, the data provided in this submission shows that the subject device is substantially equivalent to the predicate.