November 10, 2020

Jiangyin Jintech Biotech Co., Ltd.
% Stuart Goldman
Senior Consultant
Emergo Global Consulting, LLC
2500 Bee Cave Road, Building 1, Suite 300
Austin, Texas 78746

Re: K183044
Trade/Device Name: JTK Dental Implant System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: DZE, NHA
Dated: October 9, 2020
Received: October 14, 2020

Dear Stuart Goldman:

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)*
K183044

Device Name
JTK Dental Implant System

Indications for Use *(Describe)*

JTK One-Piece Integrated Implant System:

The JTK one-piece integrated 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.

JTK Two-Piece Implant System:

The JTK two-piece dental implant system is comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single tooth or multiple-tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

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.

510(k) Summary

JTK Dental Implant System

1. Submission Sponsor

Jiangyin Jintech Biotech Co., Ltd.
Building D1
No.6 Dongshengxi Road
214437 Jiangyin City
Jiangsu Province
China
Contact: Dr. Jie Zhang
Title: Founder, Chairman, CEO, General Manager

2. Submission Correspondent

Emergo Global Consulting, LLC
2500 Bee Cave Road
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Austin, TX 78746
Office Phone: (512) 327-9997
Contact: Stuart R. Goldman
Title: Senior Consultant RA/QA

3. Date Prepared

November 10, 2020

4. Device Identification

Trade Name:	JTK Dental Implant System
Common Name:	Dental implant
Classification Name:	Endosseous dental implant
Regulation Number:	21 CFR 872.3640
Product Code:	DZE
Secondary Product Code:	NHA
Class:	Class II
Classification Panel:	Dental

5. Legally Marketed Predicate and Reference Devices for the JTK Dental Implant System:

Primary Predicate Device:

- Primary Predicate: T.A.G. Dental Implant System – Crestone (K143326)

Reference Devices:

- Reference Device 1: ANKYLOS C/X Dental Implant System (K083805)
- Reference Device 2: Spectra-System Dental Implants 2008 – ScrewPlus (K090234)
- Reference Device 3: Premium Implant Systems-SHELTA Implant Systems – Premium TG (K142242)

6. Indications for Use

JTK One-Piece Integrated Implant System:
The JTK one-piece integrated 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.

JTK Two-Piece Implant System:
The JTK two-piece dental implant system is comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single tooth or multiple-tooth restorations, recognizing bone stability and appropriate occlusal load requirements.

7. Device Description

The JTK Dental Implant System is offered in two different models. These models consist of a one-piece integrated implant system where the implant and abutment are machined from the same piece of titanium, and a traditional two-piece implant system that consists of an implant and abutment that are made from different pieces titanium and held together by way of a supplied titanium screw. A titanium healing cap is also supplied with the two-piece implant system. The implants and abutments are supplied individually packaged and sterile to the end user via gamma radiation. The healing cap is packaged with the implant and the attachment screw is packaged with the abutment. All implants in the JTK Dental Implant System are made by traditional CNC manufacturing methods. For both models of the implant body, the threaded portion receives a surface modification using sandblasting and acid etching (SLA).

For the one-piece implant system, the implants are offered in two thread diameters (3.0 and 3.3 mm) and in three thread lengths (10, 13 and 15 mm). The integral abutment portion of the implant is contoured and machined, is without a surface modification, and is offered in two platform heights (4 and 6 mm).

For the two-piece implant system, the implants are offered in five thread diameters (3.8, 4.0, 4.5, 5.0 and 5.5 mm) and in four thread lengths (8, 10, 13 and 15 mm). The neck of the implant is conical in shape, 2.5 mm in height and has been machined and is without a surface modification. The two-piece implant bodies are considered a tissue level implant. The abutments that are used with the two-piece system are offered

in two different models (straight and angled (15° and 25°). The straight abutments are offered in a diameter of 4.4 mm and in lengths of 4.2, 5.2, 6.2 and 8.2 mm. The 15° angled abutments are offered in a diameter of 4.4 mm and in lengths of 6.0 and 8.0 mm, while the 25° the angled abutments are offered in a diameter of 4.4 mm and in lengths of 6.0 and 10.5 mm.

The titanium used to manufacture the one-piece and two-piece implants conform with ASTM F67, *Standard Specification for Unalloyed Titanium, for Surgical Implant Applications* while the titanium used to manufacture the abutments conform with ASTM F136, S*tandard Specification for Wrought Titanium-6Aluminum-4Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications*.

8. Substantial Equivalence Discussion

The following tables compares the JTK Dental Implant System (one-piece and two-piece designs) to the primary predicate device with respect to its indications for use, materials, surface finish, dimensions, usage, packaging, sterility, biocompatibility, shelf-life and performance testing (fatigue), and provides detailed information regarding the basis for the determination of substantial equivalence. The subject device does not raise any new issues of safety or effectiveness based on the similarities to the primary predicate device.

The following additional reference devices were used in this 510(k).

- Reference Device 1 (K083805) – The ANKYLOS C/X Dental Implant System was included as a reference device to show identical raw material (unalloyed grade 2) to the subject one-piece implant system and two-piece implant system. In addition, the abutments used in Reference Device 1 are made from Titanium alloy conforming to ASTM F136, which is the same alloy used to make the abutments in the subject two-piece implant system.

- Reference Device 2 (K090234) – The Spectra-System Dental Implants 2008 – ScrewPlus was included as a reference device to show the same implant diameters and lengths to the to the subject two-piece implant system.

- Reference Device 3 (K142242) – The Premium Implant Systems-SHELTA Implant Systems – Premium TG was included as a reference device to show similar SLA surface finish and the same implant diameters and lengths to the to the subject two-piece implant system.

Table 5-1 – Comparative Information of JTK One-Piece Implant System - Implants

Attributes	Subject Device	Primary Predicate	Reference Device 1	Similarities / Differences
Device Name	JTK Dental Implant System (One-piece implant)	T.A.G. Dental Implant System – Crestone	ANKYLOS C/X Dental Implant System	-
Manufacturer	Jiangyin Jintech	T.A.G Medical Products	Dentsply Intl., Inc.	-
510(k) #	K183044	K143326	K083805	-
Device Image				-
Indications for Use	The JTK one-piece 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 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 ANKYLOS® C/X Dental Implant System is for single- stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Dental Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, to restore chewing function. Multiple tooth applications may be splinted with a bar.	The subject and primary predicate device are indicated for the replacement of single or multiple teeth in the mandible and maxilla bone, and where appropriate, for immediate loading.
Materials	Titanium (unalloyed grade 2)	Titanium (alloy grade 23)	Titanium (unalloyed grade 2)	The subject and primary predicate device are made from different types of titanium. The difference in titanium is addressed by

				introducing Reference Device 1 (K083805), which is also made of unalloyed grade 2 titanium.
Surface Finish	SLA	SLA	SLA	The subject and primary predicate device use similar SLA surface finish technology.
Diameter (mm)	3.0, 3.3	3.0, 3.5	3.5 – 5.5, 7.0	The subject device diameters fall within those of the primary predicate device.
Threaded Length (mm)	10.0, 13.0, 15.0	10.0, 11.5, 13.0, 16.0	8 – 17, 8 – 14	The subject device lengths fall within those of the primary predicate device.
Abutment design	Contoured and polished	Contoured and polished	NA	Similar
Thread design	Straight	Tapered	Straight	This difference in thread designs between the subject device and the primary predicate device is addressed by introducing Reference Device 1 (K083805), which also has a tapered thread design.
Packaging	Single use; individual vial/PET blister package/cardboard box	Single use; individual vial/PET blister package/cardboard box	Not identified	Similar
Shelf-life	2 years	Not identified	Not identified	-

Table 5-2 – Comparative Information of JTK Two-Piece Implant System - Implants

Attributes	Subject Device	Reference Device 1	Reference Device 2	Reference Device 3	Similarities / Differences
Device Name	JTK Dental Implant System (Two-piece implant)	ANKYLOS C/X Dental Implant System	Spectra-System Dental Implants 2008 – ScrewPlus	Premium Implant Systems-SHELTA Implant Systems – Premium TG	-
Manufacturer	Jiangyin Jintech	Dentsply Intl., Inc.	Implant Direct Sybron International, LLC	Sweden & Martina S.p. A	-
510(k) #	K183044	K083805	K090234	K142242	-
Device Image					-
Indications for Use	The JTK two-piece dental implant system is comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single tooth	The ANKYLOS® C/X Dental Implant System is for single-stage or two-stage surgical procedures and cemented or screw retained restorations. The ANKYLOS® C/X Dental Implant System is intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, to restore chewing	Spectra-System Dental Implants 2008 are comprised of dental implant fixtures and prosthetic devices that compose a two-piece implant system. The implants are intended for use in the mandible and maxilla, in support of single unit or multiple unit cement or screw-receiving restorations and for the retention and support of overdentures. The implants are intended for immediate placement and function for the support of single tooth or multiple-tooth	PREMIUM Implant Systems-SHELTA Implant Systems (Premium Straight, Premium TG, Premium SP, Shelta and Shelta SL) are intended for both one-and two-stage surgical procedures. PREMIUM Implant Systems-SHELTA Implant Systems are intended for immediate placement and function on single tooth and/or multiple tooth applications when good primary stability is achieved, with appropriate occlusal loading, in order to restore chewing function. Multiple tooth	The subject and primary predicate device (K143326) are indicated for the replacement of single or multiple teeth in the mandible and maxilla bone, and where appropriate, for immediate loading. However, although the primary predicate device have indications for immediate loading, the specific wording has been chosen from Reference Device 2 (K090234) due to

	or multiple-tooth restorations, recognizing bone stability and appropriate occlusal load requirements.	function. Multiple tooth applications may be splinted with a bar.	restorations, recognizing bone stability and appropriate occlusal load requirements.	applications may be splinted with a bar. Abutments: PREMIUM-SHELTA Abutments are intended to be used in conjunction with a PREMIUM-SHELTA Implants Systems in fully edentulous or partially edentulous maxillary and/or mandibular arches. The PREMIUM-SHELTA Abutment is intended for use with an endosseous implant to support a prosthetic device in a partially or completely edentulous patient. It is intended for use to support single and multiple tooth prostheses, in the mandible or maxilla. The prosthesis can be cemented, screw retained, or friction fit to the abutment. The abutment screw is intended to secure the abutment to the endosseous implant. PREMIUM-SHELTA Abutments are compatible with PREMIUM-SHELTA Implants Systems.	the substantial equivalence related to the two-piece technological difference as compared to the primary predicate device.

Materials	Titanium (unalloyed grade 2)	Titanium (unalloyed grade 2)	Titanium (alloy grade 5)	Commercially pure grade 4 (ASTM F67)	The subject and primary predicate device are made from different types of titanium. The difference in titanium is addressed by introducing Reference Device 1 (K083805), which is also made of unalloyed grade 2 titanium.
Surface Finish	SLA	SLA	SBM (or HA)	SLA	The subject and primary predicate device and use similar SLA surface finish technology.
Diameter (mm)	3.8, 4.0, 4.5, 5.0, 5.5	3.5 – 5.5, 7.0	3.7, 4.7, 5.7, 6.5	3.3, 3.8, 4.25, 5.0	The subject device diameters fall within those of Reference Device 2 (K090234) and Reference Device 3 (K142242).
Threaded Length (mm)	8.0, 10.0, 13.0, 15.0	8 – 17, 8 – 14	8.0, 10.0, 11.5, 13.0, 16.0	6.0, 7.0, 8.5, 10.0, 11.5, 13.0, 15.0	The subject device lengths fall within those of Reference Device 2 (K090234) and Reference Device 3 (K142242).
Neck Design	Conical-shaped neck; polished	Straight; not polished	Conical-shaped neck; polished	Conical-shaped neck; polished	Similar
Thread Design	Straight with self-tapping blunt end	Straight with self-tapping blunt end	Straight with self-tapping blunt end	Straight with self-tapping blunt end	Similar

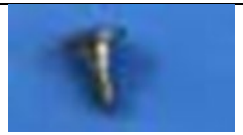
	structure	structure	structure	structure	
Connection Type	Internal hex	Keyed alignment, friction-lock taper, thread attachment	Internal hex	Internal hex	Identical
Packaging	Single use; individual vial/PET blister package/cardboard box	Not identified	Single use; individual vial/PET blister package/cardboard box	Single use; individual vial/PET blister package/cardboard box	Similar
Shelf-life	2 years	Not identified	5 years	Not identified	Similar

Table 5-3 – Comparative Information of JTK Two-Piece Implant System - Abutments

Abutments				
Attributes	**Subject Device**	**Reference Device 2**	**Reference Device 3**	**Similarities / Differences**
Device Name	JTK Dental Implant System (Two-piece implant)	Spectra-System Dental Implants 2008 – ScrewPlus	Premium Implant Systems-SHELTA Implant Systems – Premium TG	-
Manufacturer	Jiangyin Jintech	Implant Direct Sybron International, LLC	Sweden & Martina S.p. A	-
510(k) #	K183044	K090234	K142242	-
Device Image				-
Angle	0°/15°/25°	0°/15°	0°/15°/25°	The subject device abutments are of similar shape and identical angles as the abutments used in Reference Device 2 and Reference Device 3.
Materials	Titanium alloy conforming to ASTM F136	Titanium (alloy grade 5)	Not identified	The subject device abutments are made from Titanium alloy conforming to ASTM F136, which is the same alloy used to make the abutments in Reference Device

				1 (K083805).
Surface Finish	Polished	Polished	Polished	Similar
Diameter (mm)	4.4	3.7, 4.7, 5.7, 6.5	Not identified	Similar. The subject device abutment diameter falls within those of Reference Device 2 (K090234).
Length (mm)	4.2, 5.2, 6.0, 6.2, 8.0, 8.2, 10.5	5.5, 6.5, 7.5, 8.6, 9.6, 10.6	Not identified	Different. While the subject device abutment lengths of 4.2 and 5.2 mm are lower than the identified minimal length of 5.5 mm found in Reference Device 2 (K090234), the shorter lengths do not impact the substantial equivalence as the minimum length is still longer than the clinically recommended 4 mm for single unit abutments.
Connection Type	Internal hex	Internal hex	Internal hex	Identical

Table 5-4 – Comparative Information of JTK Two-Piece Implant System – Healing Cap

Healing Cap			
Attributes	**Subject Device**	**Reference Device 2**	**Similarities / Differences**
Device Name	JTK Dental Implant System (Two-piece implant)	Spectra-System Dental Implants 2008 – ScrewPlus	-
Manufacturer	Jiangyin Jintech	Implant Direct Sybron International, LLC	-
510(k) #	K183044	K090234	-
Device Image			-
Materials	Titanium alloy conforming to ASTM F136	Titanium (alloy grade 5)	The subject device abutments are made from Titanium alloy conforming to ASTM F136, which is the same alloy used to make the abutments in Reference Device 1 (K083805).
Diameter (mm)	5.0	3.7, 4.7, 5.7, 6.5	Different. While the subject device healing cap diameter of 5.0 mm is different than the identified diameters found in Reference Device 2 (K090234), this difference does not impact the substantial equivalence as the healing cap is just used to cover the internal hex portion of the conical neck during the healing process only.

Length (mm)	5.5	5.8	Different. While the subject device healing cap length of 5.5 mm is smaller than the identified length of 5.8 mm found in Reference Device 2 (K090234), the shorter length does not impact the substantial equivalence as the healing cap is just used to cover the internal hex portion of the conical neck during the healing process only.

Table 5-5 – Comparative Information of JTK Two-Piece Implant System – Attachment Screw (Bolt)

Attachment Screw (Bolt)			
Attributes	**Subject Device**	**Reference Device 2**	**Similarities / Differences**
Device Name	JTK Dental Implant System (Two-piece implant)	Spectra-System Dental Implants 2008 – ScrewPlus	-
Manufacturer	Jiangyin Jintech	Implant Direct Sybron International, LLC	-
510(k) #	K183044	K090234	-
Device Image			-
Materials	Titanium alloy conforming to ASTM F136	Titanium (alloy grade 5)	The subject device abutments are made from Titanium alloy conforming to ASTM F136, which is the same alloy used to make the abutments in Reference Device 1 (K083805).
Diameter (mm)	2.45	1.7	Different. The subject device attachment screw diameter is greater than the diameter of the attachment screw in Reference Device 2 (K090234). The device attachment, when used to connect the subject implant and abutment, passed the required fatigue testing in ISO 14801.
Length (mm)	7.8	7.2, 9.7	Different. The subject device attachment screw length of 7.8 mm falls within the identified lengths of the attachment screws used in Reference Device 2 (K090234). In addition, the device attachment, when used to connect the subject implant and abutment, passed the required fatigue testing in ISO 14801.

9. Non-Clinical Performance Data

As part of demonstrating substantial equivalence of the JTK Dental Implant System (one-piece and two-piece models) to the predicate devices (K143326 and K090234), Jiangyin Jintech conducted performance testing on their devices. The JTK Dental Implant System demonstrated substantial equivalence in the testing shown below.

- Biocompatibility Testing per ISO 10993-1 (cytotoxicity (per ISO 10993-5) and rabbit pyrogen test (per ISO 10993-11))
    - The subject devices passed all testing
- Dynamic Fatigue Testing per ISO 14801
    - The subject devices have demonstrated $5x10^6$ cycles without failure
- Sterilization Validation per ISO 11137-1, -2, and -3
    - The subject devices have demonstrated a SAL of 10^{-6} via gamma radiation
- Shelf-life Validation per ASTM F1980-07 and Packaging Validation per ISO 11607
    - The subject devices have a stated shelf-life of 2 years
- Risk Analysis per ISO 14971
    - The subject devices conform to the ISO standard
- Jiangyin Jintech have addressed all recommendations of the FDA Guidance, "Submission and Review of Sterility Information in Premarket Notifications (510(k)) Submissions for Devices Labeled as Sterile" related to LAL testing for pyrogenicity for their JTK Dental Implant System.

10. Clinical Performance Data

The non-clinical performance testing detailed in this submission supports the substantial equivalence of the subject device to the predicate devices.

11. Statement of Substantial Equivalence

The JTK Dental Implant System and the predicate devices encompass the same range of physical dimensions, including diameter and length of the implants, and the diameter and angulation of the abutments. Any minor differences in the technological features of the subject device when compared to the predicate devices have been successfully evaluated through non-clinical performance testing such that the information submitted to the FDA demonstrates that the JTK Dental Implant System is substantially equivalent to the predicate devices.