DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

February 23, 2017

Jeil Medical Corporation
Seungyoung Lee
RA Specialist
702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, Seoul, 08378
KOREA

Re: K161335
Trade/Device Name: Dual Top Screw System
Regulation Number: 21 CFR 872.3640
Regulation Name: Endosseous Dental Implant
Regulatory Class: Class II
Product Code: OAT
Dated: January 24, 2017
Received: January 25, 2017

Dear Seungyoung Lee:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K161355

Device Name
Dual Top Screw System

Indications for Use *(Describe)*
The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

JEIL MEDICAL CORPORATION
702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, 08378, Korea
Tel : +82 2 850 3533 / Fax : +82 2 850 3535

510(k) Summary

[As required by 21 CRF 807.92]

1. Date Prepared [21 CRF 807.92(a)(1)]

21 February 2017

2. Submitter's Information [21 CFR 807.92(a)(1)]

- Name of Sponsor: Jeil Medical Corporation
  - Address: 702·703·704·705·706·804·805·807·812-ho,55 Digital-ro34-gil, Guro-gu, Seoul, 08378, Korea
- Contact Name: Seungyong Lee / RA Specialist
  - Telephone No. : +82 2 850 3533
  - Fax No. : +82 2 850 3525
  - Email Address : leesy@jeilmed.co.kr
- Registration Number: 3004049923
- Name of Manufacturer: Same as Sponsor
  - Address: Same as Sponsor

3. Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

- Trade Name: Dual Top Screw System
- Common Name: Implant, Endosseous, Orthodontic
- Classification Name: Endosseous Dental Implant
- Classification Panel: Dental
- Classification Regulation: 21 CFR 872.3640
- Product Code: OAT
- Device Class: II

JEIL MEDICAL CORPORATION
702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, 08378, Korea
Tel : +82 2 850 3533 / Fax : +82 2 850 3535

4. Identification of Predicate Device(s) [21 CFR 807.92(a)(3)]

The identified predicate devices within this submission are shown as follow;

- Primary Predicate: K063495
- Applicant: Biomaterials Korea, Incorporated
- Common Name: Implant, Endosseous, Orthodontic
- Device Name: The C-Type, CT Type and Special Type

- Reference Predicate: K110392
- Applicant: PSM MEDICAL SOLUTIONS
- Common Name: Implant, Endosseous, Orthodontic
- Device Name: PSM LOMAS / BENEFIT Screws

Orthodontic Anchor Screw
There are no significant differences between the Model Dual Top Screw System and the predicate devices that would adversely affect the use of the product. It is substantially equivalent to these devices in design, function, materials, and operational principles as internal fixation components.

5. Description of the Device [21 CFR 807.92(a)(4)]

The Dual Top Screw System is a temporary fixation and screws in various configurations, shapes and sizes as follow;

	The Dual Top Screw System								
Head Design	JA Series	JB Series	G1 Series	G2 Series	JD Series	JO Series	JS Series	JF Series	JK Series
The type of orthodontic appliance	Elastic Band, Arch wire	Elastic Band, NiTi Spring	Arch wire	Elastic Band, Arch wire	Arch wire	Arch wire, NiTi Spring	Elastic Band	Elastic Band, Arch wire	Elastic Band
Length	5,6,7,8,10 ,12 mm	5,6,7,8,10 ,12 mm	5,6,7,8,10 ,12 mm	5,6,7,8,10 ,12 mm	5,6,7,8,10 ,12 mm	5,6,7,8,10 ,12 mm	10,11,12, 14,16 mm	5,6,7,8,10 ,12 mm	5,6,7,8,10 ,12 mm
diameter	Ø 1.3~ Ø 2.0	Ø 1.3~ Ø 2.0	Ø 1.3~ Ø 2.0	Ø 1.3~ Ø 2.0	Ø 1.3~ Ø 2.0	Ø 1.3~ Ø 2.0	Ø 2.0~ Ø 2.5	Ø 1.4~ Ø 2.0	Ø 1.4

The Dual Top Screw System is made of Titanium Alloy (Ti-6AL-4V), which meets ASTM F136, Standard Specification for Wrought Titanium-6 Aluminum-4 Vanadium ELI (Extra Low Interstitial) Alloy for Surgical Implant Applications, which are widely used for surgical implants with well-known biocompatibility. The head of the screw is dual head type. The head of the Dual Top Anchor System screw is designed to apply various orthodontic tools. There is a hole in the screw head through which a

702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, 08378, Korea
Tel : +82 2 850 3533 / Fax : +82 2 850 3535

wire can be passed to fix the mandible and maxilla in orthodontic treatment. Also, dual head design of screw accommodates the use of the screw with the orthodontic appliances (bracket, wire, and elastic band etc.) The sizes of the Dual Top System are diverse enough to satisfy various clinical cases. The Dual Top System screws are provided either non-sterilized or gamma-sterilized.

6. Indications for Use [21 CFR 807.92(a)(5)]

The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.

7. Technological Characteristics [21 CFR 807.92(a)(6)]

Dual Top Screw System, Endosseous Dental Implant: They share similar head, neck and thread designs as the smaller screws that are currently cleared under the predicate devices.

	Subject Device	Primary Predicate	Reference Predicate
510K Number	K161335	K063495	K110392
Product name	Dual Top Screw System	The C-Type, CT Type and Special Type Orthodontic Anchor Screws	PSM LOMAS / BENEFIT Screws
Manufacturer	Jeil Medical Corporation	Biomaterials Korea Incorporated	PSM MEDICAL SOLUTIONS
Indications for Use	The Dual Top Screw System is intended for use as a temporary anchor for orthodontic treatment for use in patients aged 12 and older.	Intended for use as a temporary anchor for orthodontic treatment.	The PSM LOMAS / BENEFIT Screws are intended to provide a fixed anchorage point for attachment of orthodontic appliances to facilitate the orthodontic movement of teeth in adolescents greater than 12 years of age and adults. The devices are used temporarily and are removed after orthodontic treatment has been completed. Screws are intended for single use only.
Design	**Screw** - Thread Diameter; Ø 1.3~ Ø 2.5 - Thread Depth: 0.15 ~ 0.55mm - Length; 5~16mm	**Screw** - Thread Diameter; Ø 1.2~ Ø 2.0 - Thread Depth: Ø 1.2: 0.14mm - Length; 5~12mm	**Screw** - Thread Diameter; Ø 1.5~ Ø 2.3 - Length; 7~15mm
Materials	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)	Titanium Alloy (ASTM F136)
Surface Treatment	No surface treatment	Anodized	Anodized

JEIL MEDICAL CORPORATION
702·703·704·705·706·804·805·807·812-ho, 55,
Digital-ro34-gil, Guro-gu, 08378, Korea
Tel : +82 2 850 3533 / Fax : +82 2 850 3535

Sterilization	Non-Sterile (Steam sterilized by user) or Gamma- Sterilized	Non-Sterile (Steam sterilization by user)	Gamma- Sterilized

The results of this testing indicate that the Dual Top Screw System is equivalent to predicate devices.

8. Non-Clinical Testing Summary

Comparative bench tests were conducted to demonstrate substantial equivalence to the primary predicate device (K063495). The following tests were conducted using FDA recognized standard methods:

- Axial Pullout test: ASTM 543
- Torsional Property test: ASTM 543
- Driving Torque test: ASTM 543

- Biocompatibility test:
The subject device is manufactured from Titanium alloy (conforming with ASTM F136) with a history of safe use. Cytotoxicity testing per ISO 10933-5 was performed to mitigate the risks associated with materials used during manufacturing

9. Clinical Testing Summary

No clinical studies were necessary for the demonstration of substantial equivalence.

10. Conclusion [21 CFR 807.92(b)(3)]

The subject device is made of the same materials and has similar dimensions and characteristics as the primary predicate device. The subject device is manufactured from material of the Titanium Alloy that is used generally in this kind of endosseous dental implant system. The subject device, Dual Top Screw System, is substantially equivalent in intended use and technological characteristics to the primary predicate device (K063495).