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

December 27, 2016

Jeil Medical Corporation
Mr. Jaehan Park
RA Manager
#702 Kolon Science Valley 2nd, 55,
Digital-ro34, Guro-gu, Seoul, 152-728
South Korea

Re: K163308
Trade/Device Name: SMARTO
Regulatory Class: Unclassified
Product Code: KIJ
Dated: November 17, 2016
Received: November 23, 2016

Dear Jaehan Park:

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,

Jennifer R. Stevenson -A

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical 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)*
K163308

Device Name
SMARTO

Indications for Use *(Describe)*
The SMARTO is intended for use in driving screws, and drilling in conjunction with craniofacial (does not include oromaxillofacial applications), craniotomnies, hand, foot, wrist and extremity reconstruction surgical procedures. It is supplied sterile and single use only.

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)]

22. November 2016

2. Submitter's Information

- Name of Sponsor: Jeil Medical Corporation
  - Address: #702 Kolon Science Valley 2nd, 55, Digital-ro34, Guro-gu, Seoul, 152-728, 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: SMARTO
- Common Name: Surgical motor unit for surgery
- Product Code: KIJ
- Device Class: Unclassified

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

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

- 510(k) Number: K101563
- Applicant: Jeil Medical Corporation
- Common Name: Surgical motor unit for surgery
- Device Name: SMARTO

Surgical motor unit for surgery
There are no significant differences between the Additional models and the predicate devices(K101563)that would adversely affect the use of the product.

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;

- 510(k) Number: K101563
- Applicant: Jeil Medical Corporation
- Common Name: Surgical motor unit for surgery
- Device Name: SMARTO

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

The SMARTO is an DC-powered device that includes a hand-held motor, switch and hold for the rotation attachment for surgery. It is supplied radiation-sterile and disposable use.

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

The SMARTO is intended for use in driving screws, and drilling in conjunction with craniofacial (does not include oromaxillofacial applications), craniotomnies, hand, foot, wrist and extremity reconstruction surgical procedures. It is supplied sterile and single use only.

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

SMARTO: With same indication and operational principle. But, dimension and specification changed some specifications of DC motor have increased for the effective use to indication under the predicate (unmodified) devices (K101563)

Non-Clinical Test Summary:

The test was conducted to verify that the proposed device met all design specifications. The test results demonstrated that the proposed device complies with the following standards and worst case criteria report:

- Electrical Safety: IEC 60601-1
- Electromagnetic Compatibility: IEC 60601-1-2
- Performance Test
  Torque: Internal standard
  Speed (RPM): Internal standard

The subject device has the same device characteristics as the predicate(unmodified) device.

Summary of the changed specification:

Part or spec.	Description of changes		Remark
Body of Product	Shape	Part of assemble with switch Part of assemble with holder assy	
Switch Rubber	Shape	Round → Square	
	Dimension	Ø 8.0 mm → width 12.5 mm	

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

Holder Assy	Shape	Part of assemble with mechanical lock	
DC Motor	Torque	24Ncm → 45Ncm	
	Speed (RPM)	160 RPM → 210 RPM	
PCB	PCB Pattern Add Switch		
Mechanical Lock	Add new part & function		
Unit of Battery (1.5V AAA Alkaline)	111-ED-050	2.0ea → 4ea	
	111-ED-031, 051	2.0ea → 3ea	
Performance (Torque)	111-ED-031	24Ncm → 30 Ncm	
	111-ED-050	24Ncm → 45 Ncm	
	111-ED-051	24Ncm → 40 Ncm	
	111-ED-052	24Ncm → 35 Ncm	
Performance (RPM)	111-ED-031	160 RPM → 250 RPM	
	111-ED-050	160 RPM → 210 RPM	
	111-ED-051	160 RPM → 165 RPM	
	111-ED-052	160 RPM → 110 RPM	

8. Substantial Equivalence [21 CFR 807.92(b)(1) and 807.92]

The subject device has the same device characteristics as the predicate (unmodified) device.

They have the same intended use, materials, energy source, design & use concept and sterilization. The differences are technical specification (Torque, Motor speed) and supply power.

However the performance and safety test data provided in this submission prove that this differences do not raise new issues in safety and performance.

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

In accordance with the Federal Food, Drug and Cosmetic Act, 21 CFR Part 807, and based on the information provided in this premarket notification Jeil Medical Corporation concludes that SMARTO is safe and effective and substantially equivalent to the predicate (unmodified) device as described herein.

END