DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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February 17, 2017

WeMED Bio-Tech Inc.
% Mr. Jeffrey Chern
SEQPRO, Inc.
2F, No.161, Minsheng West Road
Datong District.
Taipei City, 103 Taiwan

Re: K163037
Trade/Device Name: intra medullary endo-transilluminating Device (iMET device)
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: Class II
Product Code: HRX
Dated: November 28, 2016
Received: December 5, 2016

Dear Mr. Chern:

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 -S

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)*
K163037

Device Name
Intra medullary endo-transilluminating device (iMET) device

Indications for Use *(Describe)*
The Intra medullary endo-Transilluminating device (iMET), together with all its components, is for use in performing interlocking screw holes positioning during intra-medullary nailing procedure. It is designed to assist surgeons who need to fix fractured long bone , such as tibia, femur, or humerus by providing illumination intramedullary for rapid and precise screw holes positioning without using C-arms thus no extra radiation dosage was absorbed.

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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K163037 - 510(k) Submission

intra medullary endo-transilluminating device (iMET device)

510(k) Summary

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of the iMET device.

The Assigned 510(K) Number: K163037
Date Prepared: 2016/10/19

Submitted by WeMED Bio-Tech Inc.
Rm. D, 7F., No.96, Hougang St., Shilin Dist., Taipei City 111-70, Taiwan (R.O.C.)
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1. Product Information

Proprietary Name：Intra medullary endo-transilluminating device
Common Name：Arthoscope
Reviewing Panel：Orthopedic
Classification Name：Class Ⅱ
Product Code: HRX
Regulatory Section: 888.1100

2. Identification of the Predicate Device :

Predicate Device Name : ITALITE , MODEL 500-3.1, 550-3.1, 600-3.1, 650-3.1, 450-2.0,400-2.0
Manufacturer : JG MEDICAL PRODUCTS LLC

Product Code : HRX
510(k) Number : K070021

3. Indication for Use

The Intra medullary endo-Transilluminating device (iMET device), together with all its components, is for use in performing interlocking screw holes positioning during intra-medullary nailing procedure. It is designed to assist surgeons who need to fix fractured long bone , such as tibia, femur, or humerus by providing illumination intramedullary for rapid and precise screw holes positioning without using C-arms thus no extra radiation dosage was absorbed.

4. Device Description

The intra medullary endo-transilluminating (iMET) device is designed to aid the positioning of interlocking nails distal screw hole while intra-medullary nailing procedure is performed. It is a device used to assist surgeons who need to fix the fractured bone more efficiently. It is single use and is disposable after the operation.

The whole system consists of a LED-embedded guide pin (iMET), connecting cable and a power control box. The iMET will provide essential light source and indicated the route for aiming and tightening interlocking screw.

The iMET consists of a LED lamp, a 304 stainless metal tube and a Polyetheretherketone (PEEK) head. The PEEK comes from ZELLAMID® 1500, ZELLAMID® 1500 X, which is polyetheretherketone (PEEK by ISO 1043) in compliance with the EU-Directive (EU) 10/2011 of 14th January 2011 related to “plastic materials and articles intended to come into contact with foodstuffs” and its amendments, and including the Regulation (EC) No 1935/2004, both in their relevant versions. The composition of the product also complies with the requirements of the Bedarfsgegenständeverordnung BGV (German ordinance) in the revised version of 23.12.1997 (Monomers and other starting substances) as amended. Besides, it is in compliance with the appropriate regulation of Food and Drug Administration (FDA) in USA for contact with food and with the requirements of FDA-Code of Federal Regulations 21 CFR 177.2415. As for the 304 Stainless Steel, it meets the specifications of ASTM E1479-99 (Reapproved 2005) and ASTM E1019-11.

The connecting cable is a simple 2 lines cable with custom-made IP67 waterproof connectors for repeated usage under basic disinfection.

There is foolproof design in both connectors of the cable in order not to plug in the wrong way. The power source, control box, provide electric power for LED. It is designed within a metal box. The voltage enhancement and circuit design were applied for controlling high efficiency LED. The power input is DC 4.5V provided by 3 AA batteries and the output is 30mA in maximum. The control box can be reused under basic cleaning process after the operation.

5. Summary of Performance Tests

The table below summarizes the safety tests conducted:

Type of Testing	**Method Used**	**Results / Conclusion**
Biocompatibility	ISO 10993	Provided as Biocompatibility Report
Sterilization Validation Test and Shelf Life	ISO 11137/ ISO11607	Provided as Sterilization Validation Report
Electromagnetic Compatibility and Electrical Safety	IEC 60601/IEC 60601-1-2	Provided as Electromagnetic Compatibility and Electrical Safety Report

As for performance testing, 5 pieces of the iMET devices were inserted into both cow femur and artificial femur cavities in order to detect the position of the tip of the guide pin. The light penetrates out of the cow femur and the 3D-printed artificial femur (ABS) surface, revealing the position of the guide pin. All devices met the following acceptance criteria:

1. The iMET device is functionable when connected to the controller;
2. Light penetration is observed for both cow femur and artificial femur;
3. The red intensity value of the light spot in the image recorded by a digital microscope is at least 255 (R values).

The compatibility between the materials used and biological tissues, cells and body fluids was tested by PIDC Verification Testing Laboratory which is complied with the Taiwan MOHW GLP(2006), OECD-GLP (ENV/MC/CHEM(98)17,1997) and U.S.FDA(21 CFR Part 58, 2015) on principles of Good Laboratory Practice for Nonclinical Labotory Studies and meet the requirements of performance standard ISO 19003-5: 2009, ISO 10993-10:

2010 and ISO 10993-11: 2006. Cytotoxicity test was conducted according to ISO 10993-5:2009; sensitization test was conducted according to ISO10993-10:2010; acute toxicity test was conducted according to ISO 10993-11:2006 and hemolytic test was conducted according to ASTM F756-13. The test results indicate that iMET device show no adverse effect in terms of cytotoxicity, sensitization, irritation, acute toxicity and hemolytic test. For completed biocompatibility testing information, please refer to section 15 for details.

The gamma irradiation of sterilization is adapted for the iMET devices. 25kGy was substantiated in accordance with ISO 11137-2 Sterilization of health care products-Radiation-Part 2: Establishing the sterilization dose. The sterilization validation study was conducted to validate and conform the sterile effect required by the standard. The validation was conducted by China Biotech Corporation, a qualified Taiwan GMP Contract Manufacturer. Besides, the shelf life study was conducted on the original packaging of sterile finished products, Intra medullary endo-transilluminating device (iMET device). After sterilization, the whole sterile packages were placed into the aging Incubator, and incubated for 23 days under controlled conditions (55°C) simulating the real time aging of 6 months. After accelerated aging study, the integrity of product packaging were demonstrated by investigating the seal peel strength, burst & creep, dye penetration of packages.

The electromagnetic compatibility of the intra medullary endo-transilluminating device (iMET device) was tested by the Electrical Testing Center (ETC) according to IEC/EN60601-1-2:2007. The electrical safety of the intra medullary endo-transilluminating device (iMET device) was tested by the Underwriters Laboratories Taiwan, Co. according to IEC60601-1:1988+A1:1999+A2:1995. iMET device was in compliance with both aformentioned standards.

6. Comparison to Predicate Device

The iMET device is compared to the predicate device, ITALITE (assigned 510(k) number: K070021) in terms of intended use, indications for use and design features.

The iMET device is a rigid type device intended for illumination for surgeons in performing rapid and precise screw holes positioning without using C-arms during

intra-medullary nailing procedure. Its predicate device, ITALITE is intended for for illumination during joint examinations, arthroscopies, biopsies, in minimally invasive procedure of the knee, shoulder, temporal mandibular joint, ankle, and elbow. The contraindications for both devices are not know at this time. Both devices are single-use, disposable devices without software.

The iMET (800mm) is longer than ITALITE (400-650 mm).
The components of iMet consist of thin walled 304 stainless steel tube, PEEK and epoxy/UV glue, whereas its predicate device is made from thin walled stainless steel tube (3.1mm or 2.0mm) and epoxy glue.

The light source of the iMET device is LED mounted within PEEK head in front of the 304 stainless steel tube. The LED is powered (DC) by the control box. The predicate device, ITALITE has off-the-shelf light source manufactured by ACMI, Wolff, Stortz and Olympus, with a stainless steel knob at the proximal end, for placement and direction use.

The iMET is tested according to IEC 60601-1, IEC 60601-1-2 and IEC 60601-2-18, whereas its predicate, ITALITE is tested according to IEC60601-2-18.

The iMET is delivered as sterile device further to Gamma irradiation. Its predicate, ITALITE is sold as non-sterile device.

The iMET device is substantially equivalent to the predicate device, ITALITE. The subject device has the same indications for use and clinical utility, and similar design principles, materials, and packaging as the predicate device. The table below provides a comparison between the subject device and the predicate device.

Product Name	**New Device** iMET device	**Predicate Device** ITALITE	Judgement
Regulation number & product code	888.1100 HRX	888.1100 HRX	Same
510(k) Num.	K163037	K070021	

Components	Rigid type device	Semi-rigid device	Similar, the components of iMET passed related safety tests in compliance with related recognized standards
Intended use	Illumination	Illumination	Same
Indication for use	The device is intended to used as illumination source for surgeons in performing rapid and precise screw holes positioning without using C-arms during intra-medullary nailing procedure.	Intended for illumination during joint examinations, arthroscopies, biopsies, in minimally invasive procedure of the knee, shoulder, temporal mandibular joint, ankle, and elbow. It is for illumination only and is not indicated for viewing.	Similar. Although the indication usage described in ITALITE including joint examinations and arthroscopies illumination, it is actually for illumination in interlocking nailing procedure.
Appearance	Length :800 mm	Length:400-650 mm	Similar, the iMET is longer than ITALITE due to surgeons' suggestion for easier holding when performaning

			distal screw holes positioning.
Component Materials	1. Thin walled 304 stainless steel tube 2. PEEK 3. Epoxy/UV glue	1. Thin walled Stainless steel tube (3.1mm or 2.0mm) 2.Epoxy glue	Similar, the PEEK is in compliance with ISO 1043 and the stainless stain meets the specifications of ASTM E1479-99 (Reapproved 2005) and ASTM E1019-11
Power of Light Source	1. Light source come from LED 2. mounted within PEEK head in front of the 304 stainless steel tube. 3. The control box will provide eletric power (DC) for the LED.	1. Light source come from other off-the-shelf light source which manufactured by ACMI, Wolff, Stortz and Olympus. 2. Stainless steel knob at the proximal end, for placement and direction use.	Similar, the iMET device delivers fan beam of the visible red light so that it is more efficient for surgeons to see the light spot on the bone surface when inserting the device into the nail. Also, iMET deliver red light (~640 nm)

			illumination which has less absorption rate for human tissue, thus the light penetration to bone is better.
Performance Standards	IEC 60601-1 IEC 60601-1-2 IEC 60601-2-18	IEC 60601-2-18	Similar, iMET is in compliance with related recognized standards
Sterilization	Gamma Sterilization	Sold non-sterile. User sterilize before use.	Similar, iMET is in compliance with related recognized standard
Use	Single use and disposable.	Single use and disposable.	Same
Software	No software or firmware	No software or firmware	Same
Contra-Indications	Not known at this time	None known at this time	Same

Both subject and predicate devices are same in intended use and indications for use. Since we could hardly get the predicate from the market(probably the device has phased out of the market), we tried to demonstrate the safety of the device by conducting the tests according to related FDA recognized standards which were also adopted by the manufacturer of the predicate device. All the safety tests passed. Besides, Bench and clinical performance testing were conducted to ensure that iMET device met the need of the patient and doctors for safer and easy to operated intra-medullary nailing device.

In conclusion, we propose that iMET device is substantially equivalent to its predicate device, ITALITE (K070021).

7. Usability test in Clinical Environment

A clinical trial was conducted at Cheng Hsin Rehabilitation Medical Center, Beitou, Taipei, Taiwan, to develop a fluoroscopy-free technique that would aid the positioning of intra-medullary interlocking screws. Biological tissues are translucent to light over the wavelength range from 700 to 1000 nm; based on this unique feature we demonstrated that the iMET device that was able to aid distal interlocking. By directing a light source inside the bone cavity near a targeted screw hole, a portion of the light is able to penetrate through the hole and the outer bone surface. It can then be detected in situ and in real time by an external observer with naked eyes.

Institutional review board approval was obtained for this study. A total of 19 (11 males and 8 females) consecutive tibia-fracture patients were recruited for the study. All fractures were stabilized with intra-medullary nails (Osteo, Selzach, Switzerland). The average age of the patients was 26.5±6.2 years. The diameter of the implants ranged from 9 to 12 mm. In all cases, evaluation was carried out based on the failure rate and operation times. Failure rate is defined as the number of repeated drilling attempts divided by number of cases. In addition, the time required to place the distal interlocking screw and to complete the iMET-based intra-medullary nailing procedure were separately documented.

No fluoroscopy was required for placing the distal interlocking screw and no repetitive drilling or insertion of the transverse interlocking nail was needed. Thus the failure rate was 0% (0/19). The average time to finish inserting one distal interlocking screw was 4.1±1.8 min. The mean total operation time was 49.1±11.7 min. With iMET, the average time required to complete the placing of one distal interlocking screw was shorter than what have been reported (ranging from 16.7 to 19.1 min) when using other types of TADs.

7. Conclusion

The iMET device is compared to the predicate device, ITALITE (assigned 510(k) number: K070021) in terms of intended use, indications for use and design features.

The iMET device is a rigid type device intended for illumination for surgeons in

performing rapid and precise screw holes positioning without using C-arms during intra-medullary nailing procedure. Its predicate device, ITALITE is intended for for illumination during joint examinations, arthroscopies, biopsies, in minimally invasive procedure of the knee, shoulder, temporal mandibular joint, ankle, and elbow. The contraindications for both devices are not know at this time. Both devices are single-use, disposable devices without software.

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