April 30, 2021

JACE Medical, LLC
℅ Dawn N. Norman
Partner
MRC Global
9085 E. Mineral Circle, Suite 110
Centennial, Colorado 80112

Re: K210290
Trade/Device Name: JACE Medical Thoracic Plating System
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS
Dated: February 1, 2021
Received: February 2, 2021

Dear Dawn Norman:

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,

Shumaya Ali, MPH
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma Devices
OHT6: Office of Orthopedic 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)*
K210290

Device Name
JACE Medical Thoracic Plating System

Indications for Use *(Describe)*
The JACE Medical Thoracic Plating System is indicated for use in the stabilization and fixation of fractures of the chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, trauma, or planned osteotomies.

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.

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510(k) Summary

JACE Medical Thoracic Plating System

April 01, 2021

I. SUBMITTER INFORMATION

Name of Sponsor:	JACE Medical, LLC
Address:	3516 Commerce Drive Warsaw, IN 46580
Primary Contact:	Dawn Norman, Partner MRC Global, LLC
Phone:	618-604-3064
Email:	Dawn.Norman@askMRCGlobal.com
Company/Secondary Contact:	Scott Steffensmeier
Phone:	574-527-9427

II. DEVICE

Trade Name:	JACE Medical Thoracic Plating System
Common Name:	Plate, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (21 CFR 888.3030)
Regulatory Class:	Class II
Panel:	Orthopedic
Product Code:	HRS

III. PREDICATE DEVICES

Primary Predicate:

- Zimmer Biomet, Sternalock/Sternalock Blu-Biomet Microfixation Sternal Closure System (Sternalock), K121302

Additional Predicates:

- JACE Medical, JACE Sternal Closure System, K142484
- Ethicon, Inc., Stainless Steel Suture Wire, K170767

IV. DEVICE DESCRIPTION

The JACE Medical Thoracic Plating System consists of plates and accessories designed to provide fixation following sternotomy and sternal reconstructive

surgical procedures, trauma, or planned osteotomies. The system includes instrumentation which has been specifically designed for use with this system of implant. The system is comprised of an assortment of various plate configurations, locking screws, and accompanying instrumentation. Variants of the plates include flat and pre-contoured concave and convex plates. Plates may be bent to fit patient anatomy. Plates are secured using previously cleared JACE self-drilling locking bone screws (K142484), which are offered in a single diameter of 3.5mm and have a range of lengths from 10mm to 20mm. There are no changes to the screws and they are not within the scope of this 510(k). Like the predicate device, all implant components are manufactured from titanium alloy (Ti-6-Al-4 ELI) per ASTM F136. All implants in the JACE Medical Thoracic Plating System are intended for single use only. The plates, screws, and all associated instrumentation will be provided non-sterile, to be steam sterilized by the end user. MR compatibility has been established.

V. INDICATIONS FOR USE

The JACE Medical Thoracic Plating System is indicated for use in the stabilization and fixation of fractures of the chest wall including sternal fixation following sternotomy and sternal reconstructive surgical procedures, trauma, or planned osteotomies.

The Indications for Use statement for the JACE Medical Thoracic Plating System is not identical to the predicate device; however, the differences do not alter the intended therapeutic use of the device nor do they affect the safety and effectiveness of the device relative to the predicate. Both the subject and primary predicate device have the same basic intended use for the treatment of fractures of the chest wall, by stabilization and fixation through attachment of plates.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTIS WITH THE PREDICATE DEVICE

The subject JACE Medical Thoracic Plating System components are substantially equivalent with respect to indications for use, design, dimension, principles of operation, general surgical technique and materials to the primary predicate and the JACE Sternal Closure System, previously cleared by the FDA.

There are insignificant differences between the subject device and primary predicate device. The subject device plate thickness range and screw diameter slightly differs from the predicate device. The subject device has a range of screw lengths of 10-20mm while the primary predicate has screw lengths from 8-20mm. Additionally, the subject device and primary predicate device each have multiple geometric configurations for plate shapes. While many plates have the same or similar configurations, the subject device and primary predicate systems do not contain the exact same configurations.

VII. PERFORMANCE TESTING

The following performance testing was performed on the subject device in support of substantial equivalence to the primary predicate device.

Biocompatibility

A biological evaluation has been performed in accordance with ISO 10993:2018. The predicate device is an implanted device that is in contact with tissue and bone for greater than 30 days. The JACE Medical Thoracic Plating System plates are fabricated from Titanium Alloy (ASTM F136) identical to that of the original JACE Medical Sternal Closure System (K142484).

Magnetic Resonance Testing

Non-clinical testing is provided to support the conditional safety of the JACE Medical Thoracic Plating System components in the MR environment including:

- Radio frequency heating (ASTM F2182-19e2)
- Image artifacts (ASTM F2119-13)
- Magnetically induced displacement force (ASTM F2052-15)
- Torque (ASTM F2213-17).

Non-Clinical Test Summary

Bench tests were conducted to verify that the subject device met all design specifications:

- Theoretical Stress Analysis
- Longitudinal Shear-Static
- Lateral Distraction-Static and Cyclic
- Four-Point Bending (ASTM F382-17)

Clinical Test Summary

No clinical studies were conducted.

VIII. CONCLUSIONS

Based on the information submitted, the JACE Medical Thoracic Plating System is substantially equivalent to the currently marketed devices. The subject device and primary predicate device are made of similar materials and have similar design and characteristics. Therefore, the subject device is as safe, as effective, and performs as well or better than the legally marketed primary predicate device.