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

October 3, 2013

Beijing Libeier Bio-Engineering Institute Company, Limited
% Ms. Diana Hong
General Manager
Mid-Link Consulting Company, Limited
P.O. Box 120-119
Shanghai, 200120
CHINA

Re: K132642
Trade/Device Name: Locking Plate 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, HWC
Dated: August 23, 2013
Received: August 26, 2013

Dear Ms. Hong:

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

Digitally signed by Jighili Tatiana
Date: 2021.04.13 09:37:28 EEST
Reason: MoldSign Signature
Location: Moldova

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 Small Manufacturers, International and Consumer Assistance 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" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

for Erin I. Keith

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2 Indications for Use

510(k) Number: K132642
Device Name: Locking Plate System

Indications for Use:

Locking Plate System can be used for adult patients with age above 21 as indicated for fixation of fractures, including ulna, radius, humerus, femur tibia and fibula.

☒PRESCRIPTION USE (Part 21 CFR 801 Subpart D) OR ☐OVER-THE-COUNTER USE (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Elizabeth L. Frank -S

Division of Orthopedic Devices

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2040507-1

Organization: Beijing Libeier Bio-Engineering Institute Co., Ltd.
Suite 2, 201-220, 100 6th Kechuang Street,
Economic and Technological Development Area,
100176 Beijing, P.R. China

Scope: Design and Development, Manufacture and Distribution of Bone Plates, Bone Screws, Interlocking Intramedullary Nails, Spinal Fixation Systems, Spinal Interbody Fusion Cages, Orthopaedic Bone Wires, Orthopaedic Bone Pins, Universal External Fixation Systems and Orthopedic Manual Surgical Instruments

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 16803311 010

Effective date: 2020-10-16

Expiry date: 2023-08-04

Issue date: 2020-10-16

TÜV Rheinland LGA Products GmbH Certification Body

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex II excluding (4)

Registration No.:	HD 2040507-1
Manufacturer:	Beijing Libeier Bio-Engineering Institute Co., Ltd. Suite 2, 201-220, 100 6th Kechuang Street, Economic and Technological Development Area, 100176 Beijing, P.R. China
Products:	Non-sterile Orthopaedic Bone Pins, Non-sterile Orthopaedic Bone Wires, Non-sterile Bone Plates, Non-sterile Bone Screws, Non-sterile Spinal Fixation Systems, Non-sterile Interlocking Intramedullary Nails and Non-sterile Spinal Interbody Fusion Cages

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II section 4 is required.

Report No.:	16803311 011
Effective date:	2021-02-25
Expiry date:	2024-05-26
Issue date:	2021-02-25

Jing Zhang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Beijing Libeier Bio-Engineering Institute Co., Ltd.
Suite 2, 201-220, 100 6th Kechuang Street, Economic and Technological Development Area, 100176 Beijing, P.R. China

Contact

Tel. +49 911 655-5225
Mail: service
@de.tuv.com

Date February 25, 2021

Application for: Production Quality Assurance
Certificate No. : HD 2040507-1
Requirement : MDD Annex II excluding section 4

Dear Madam or Sir,

Your Quality Management System has been audited and fulfills the above-mentioned requirement.

Enclosed please find the certificate No. HD 2040507-1.

Best regards,

Jing Zhang
Certification body

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Jörg Mähler, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dipl.-Ing. Ralf Scheller