November 9, 2021

Bespa Global, LLC
℅ Katelyn Jessup
Regulatory & Quality Specialist
Kapstone Medical, LLC
520 Elliot St.
Charlotte, North Carolina 28202

Re: K202326
Trade/Device Name: BESPA Charcot System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC
Dated: October 7, 2021
Received: October 8, 2021

Dear Katelyn Jessup:

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, M.P.H.
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)*
K202326

Device Name
BESPA Charcot System

Indications for Use *(Describe)*
The The BESPA Charcot System is indicated for fracture fixation, reconstruction procedures, arthrodesis, and osteotomies of various bones and bone fragments in the foot and ankle, including metatarsals and tarsals. For example, medial and/or lateral column fusion as a result of neuropathic osteoarthropathy (Charcot). The BEPSA Charcot System is intended for use in adult populations.

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 – K202326

In accordance with Title 21 of the Code of Federal Regulations, Part 807, and in particular 21 CFR 807.92, the following summary of information is provided.

1. Date of Preparation

November 9, 2021

2. Applicant

BESPA Global, LLC
9 Rand Road
Cape Elizabeth, Maine 04107

3. Submitter/Contact Person

Katelyn Jessup
Regulatory and Quality Specialist
Kapstone Medical LLC
520 Elliot St.
Charlotte, NC 28202
Phone: 704-843-7852

4. Device Name

Trade Name: BESPA Charcot System
Common Device Name: BESPA Charcot System
Classification Name: Smooth or Threaded Metallic Bone Fixation Fastener
Regulation Number: 888.3040
Product Code: HWC
Common Name: Screw, Fixation, Bone
Classification: Class II
Panel: Orthopedic

5. Predicate Devices

Wright Medical Salvation Beams and Bolts System (K140741) – Primary
Smith & Nephew Cannulated Screws and Washers (K111994)

6. Intended Use (Intended Purpose and Conditions of Use)

The BESPA Charcot System is intended to treat Charcot deformity in the foot. It consists of the Medial & Lateral Segmental Columns. The system is used to align and secure various bones in the foot. The BESPA Charcot System is for prescription use only.

7. Indications for Use

The BESPA Charcot System is indicated for fracture fixation, reconstruction procedures, arthrodesis, and osteotomies of various bones and bone fragments in the foot and ankle, including metatarsals and tarsals. For example, medial and/or lateral column fusion as a result of neuropathic osteoarthropathy (Charcot). The BEPSA Charcot System is intended for use in adult populations. The device is for prescription use only.

8. Device Description

The BESPA Charcot System is offered non-sterile and consists of implants and system-specific instruments.

The Segmental Column is composed of various modular cylindrical components which screw together to create an implant assembly of the surgeon's desired features. The system contains transverse screws of various lengths. The implant construct has a compression capability.

All implants are made of titanium alloy.

9. Comparison of Technological Characteristics with the Predicate Devices

As was established in this submission, the subject device BESPA Charcot System is substantially equivalent to the predicate device, cleared by the FDA for commercial distribution in the United States. The subject device was shown to be substantially equivalent and have the same technological characteristics to its predicate device through comparison in areas including design, intended use, material composition, function, and sterility.

10. Performance Data

There are no clinical data generated and held by the manufacturer, i.e., no pre-marketing or post-market clinical studies or animal studies have been performed. The following information is provided in support of substantial equivalence.

10.1 Biocompatibility

The subject device BESPA Charcot System is classified as an implant device with tissue/bone contact and permanent contact. Therefore, according to ISO 10993-1 the biological evaluation was assessed for potential effects. The BESPA Charcot System devices are manufactured from Ti-6AI-4V ELI conforming to ASTM standard F136. The evaluation was based on raw material data, biocompatibility testing according to the applicable ISO 10993 standards, and published literature.

The results show that implants made of Ti-6AI-4V ELI have a high demonstrable biological safety. No concerns arose that would preclude clinical use of the BESPA Charcot System. The accessories are classified as externally communicating medical devices with tissue/bone contact and less than 24 hours contact. All used materials have a medical grade. The requirements of the ISO 10993 standard are fulfilled.

10.2 Mechanical Testing

Testing was performed to demonstrate equivalence to other cleared fixation devices and bone screws, or to meet physiologically relevant acceptance criteria, according to the standards below.

- ASTM F1264 “Standard Specification and Test Methods for Intramedullary Fixation Devices”
- ASTM F543 “Standard Specification and Test Methods for Metallic Medical Bone Screws”
- ASTM F384 “Standard Specifications and Test Methods for Metallic Angled Orthopedic Fracture Fixation Devices”

11. Conclusion

The BESPA Charcot System and the predicate device Wright Medical Salvation Beams and Bolts System (K140741) have the same “Indications for Use,” are available by prescription only, and are provided non-sterile. Any technical differences, which were identified, do not result in new questions of safety or effectiveness.

Through assessment of technological characteristics, indications for use and performance data, it can be concluded that BESPA Charcot System is both a safe and effective device and is substantially equivalent to the Salvation Beams and Bolts System.