April 14, 2020

BAUI Biotech Co., Ltd.
Jessy Lin
Regulatory Affairs Specialist
6F., No.8, Sec.1, Zongxing Rd., Wugu Dist.,
New Taipei City, 24872
Taiwan

Re: K191353
Trade/Device Name: COMET Lumbar Interbody Fusion Cage
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: March 17, 2020
Received: March 20, 2020

Dear Jessy Lin:

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,

Brent L. Showalter, Ph.D.
Assistant Director (Acting)
DHT6B: Division of Spinal 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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K191353

Device Name
COMET Lumbar Interbody Fusion Cage

Indications for Use *(Describe)*
The COMET Lumbar Interbody Fusion Cage is indicated for use in intervertebral body fusion of the spine. The COMET Lumbar Interbody Fusion Cage is inserted via a transforaminal posterior lumbar fusion procedures in skeletally mature patients with degenerative disc disease (DDD defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) and intended for use with autogenous bone graft at one or two contiguous levels of the lumbosacral spine (L2-S1). The COMET Lumbar Interbody Fusion Cage is intended to be used with supplemental fixation systems cleared by the FDA for use in the lumbar spine. Patients should have at least six months of non-operative treatment prior to surgery. In addition, these patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

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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V. 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of 21 C.F.R. §807.92.

Submitter's Name: BAUI BIOTECH CO., LTD.

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Submitter's Telephone: 886-2-8976-9538

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Date Summary was Prepared: March. 17th , 2020

Trade or Proprietary Name : COMET Lumbar Interbody Fusion Cage

Common or Usual Name: Interbody fusion cage, Intervertebral cage, Spacer

Classification Name: Intervertebral body fusion device.

Classification: Class II per 21 CFR 888.3080

Product codes: MAX

Predicate Device: SYNTHES T-PAL SPACER (K100089)

Device Description:

The COMET Lumbar Interbody Fusion Cage is a hollow, bullet-shaped PEEK cage (per ASTM F2026) with three Tantalum marker pins (per ASTM F560). It is indicated for use in

skeletally mature patients for the lumbar spine intervertebral fusion. It is angulated 4°to accommodate the lordotic curve (except for the smallest height of each footprint, which does not have a lordotic angle.) The Cage devices are offered in a variety of different sizes with varying footprint dimensions to accommodate a multitude of anatomical needs. The implant has serrations on the top and bottom for fixation and the hollow space of the implant is intended to hold autogenous bone graft for fusion purposes. The COMET Lumbar Interbody Fusion Cage is supplied "Sterile".

Indications for Use:
The COMET Lumbar Interbody Fusion Cage is indicated for use in intervertebral body fusion of the spine. The COMET Lumbar Interbody Fusion Cage is inserted via a transforaminal posterior lumbar fusion procedures in skeletally mature patients with degenerative disc disease (DDD defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies) and intended for use with autogenous bone graft at one or two contiguous levels of the lumbosacral spine (L2-S1). The COMET Lumbar Interbody Fusion Cage is intended to be used with supplemental fixation systems cleared by the FDA for use in the lumbar spine. Patients should have at least six months of non-operative treatment prior to surgery. In addition, these patients may have up to Grade I spondylolisthesis or retrolisthesis at the involved level(s).

Substantial Equivalence:
The COMET Lumbar Interbody Fusion Cage is substantially equivalent to the SYNTHES T-PAL SPACER, the predicate legally marketed device (K100089). The substantial equivalence of this device is based on equivalence in intended use, materials, designs and operational principles to the listed predicate device.

Testing was performed to support the equivalence of the intervertebral body fusion device in accordance with FDA Guidance "Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Intervertebral Body Fusion Device" The following test was performed in accordance with ASTM F2077: Test Methods For Intervertebral Body Fusion Devices and ASTM F2267 Standard Test Method for Measuring Load Induced Subsidence of Intervertebral Body Fusion Device Under Static Axial Compression with particular requests in Static Compression, Static Compression Shear, Dynamic Compression, Dynamic Compression Shear and Subsidence.

Comparison of Technological Characteristics Equivalence:

The subject COMET Lumbar Interbody Fusion Cage has the same indications for use statements and functions as well. The dimension angle is less than the predicate device. But both design features are similar, hollow design to accommodate a bone graft and teeth serration to stable the construct.

The COMET Lumbar Interbody Fusion Cage is composed of the same PEEK material as the predicate device, however, the material of marker pin of COMET Lumbar Interbody Fusion cage used Tantalum which is different from predicate device (Ti6Al7Nb), but both Tantalum and TAN (Ti6Al7Nb) are a good radiopaque solution as they offer strong radiographic opacity and excellent biocompatibility applying in medical device. No matter which material is used, both materials of marker pin allow exact determination of the position of the implant during surgery.

The COMET Lumbar Interbody Fusion Cage and predicate devices have nearly identical technological characteristics and the minor differences do not raise any new issues of safety and effectiveness.

Table 5-1 Predicate Devices

510k Number	Trade or Proprietary or Model Name	Manufacturer	Predicate Type
K100089	SYNTHES T-PAL SPACER	SYNTHES SPINE	Primary

Non Clinical Testing:

The worst-case size for the COMET Lumbar Interbody Fusion Cage was conducted in the following mechanical test modes:

- Static Compression per ASTM F2077
- Static Compression Shear per ASTM F2077
- Subsidence per ASTM F2267
- Expulsion
- Dynamic Compression per ASTM F2077
- Dynamic Compression Shear per ASTM F2077

Above non-clinical performance data was provided in support of substantial equivalence of the subject device.

Conclusions:

The subject COMET Lumbar Interbody Fusion has identical indication for use, and similar technological characteristics, principles of operation as the predicate. The modifications raise no new types of safety or effectiveness questions. The overall technology characteristics lead to the conclusion that the COMET Lumbar Interbody Fusion is substantially equivalent to legally marketed predicate device.