September 14, 2021

Baat Medical Products BV
Martjin Heikens
Regulatory Affairs Manager
F. Hazemeijerstraat 800, Building A04
Hengelo, Overijssel 7555RJ
Netherlands

Re: K211474
Trade/Device Name: Kleiner KG2 System
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: MAX
Dated: August 23, 2021
Received: August 26, 2021

Dear Martjin Heikens:

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,

for
Brent Showalter, Ph.D.
Assistant Director
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K211474

Device Name
Kleiner KG2 System

Indications for Use *(Describe)*
The KG2 implant is indicated for transforaminal and posterior interbody fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1 spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The KG2 implant is used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The interbody fusion devices are intended to be used with FDA-cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

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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BAAT MEDICAL Products BV
F. Hazemeijerstraat 800
7555 RJ Hengelo
The Netherlands

5. Traditional 510(k) Summary

1. Applicant/Submitter

Submitter Name: BAAT Medical Products BV

Submitter Address: F. Hazemeijerstraat 800 - Building A04
7555 RJ Hengelo
The Netherlands

Phone Number: +31-(0)88-5656600

Contact person: Kelsey van Abbema

Date Prepared: 08-SEPT-2021

2. Device

Device Trade name: Kleiner KG2 System

Classification: Intervertebral body fusion device (21 CFR 888.3080)

Product Code: MAX

Review Panel: Orthopedic

3. Predicate device:

Primary predicate device:
Osseus Aries-TC and Aries-TS system (K181347)

Additional predicate devices:
Stryker (K2M), Mojave system (K193203)
NuVasive MLX system (K173025)

4. Device Description

The Kleiner KG2 is a cage intended for lumbar intervertebral fusion (PLIF/TLIF approach). The design contains both solid and porous structures formed as a diamond mesh, and it contains a bone grafting hole. The cage is additively manufactured from titanium alloy. The KG2 cage may be used with coverplate.

The sterile Kleiner KG2 implant comes pre-assembled on the inserter and includes pre-packaged sterile, single-use instrumentation for primary insertion, graft passing, and cover plate insertion. A reusable set of instruments are included for disc preparation, trial sizing, and repositioning/removal.

5. Intended Use/Indication for Use Statement

The KG2 implant is indicated for transforaminal and posterior interbody fusion of the spine in skeletally mature patients with degenerative disc disease (DDD) and up to Grade 1

spondylolisthesis of the lumbar spine at one level or two contiguous levels. DDD is defined as back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies. The KG2 implant is used to facilitate interbody fusion in the lumbar spine from L2 to S1 using autogenous and/or allogenic bone graft comprised of cancellous and/or corticocancellous bone graft to facilitate fusion. The interbody fusion devices are intended to be used with FDA-cleared supplemental fixation designed for the implanted level. Patients should have at least six months of non-operative treatment prior to treatment with an interbody fusion device.

6. Summary of Technological Characteristics of Device Compared to Predicate devices

- Intended Use: The Kleiner KG2 System and all the predicates have similar intended uses.
- Materials: The Kleiner KG2 System is fabricated from the same material as the predicate device
- Design Features/Functions: The Kleiner KG2 System and cited predicate devices share similar basic design features and functions.
- Dimensions: The Kleiner KG2 System is dimensionally similar to cited predicate devices.
- Performance Specification: Mechanical testing confirmed the Kleiner KG2 System demonstrated equivalent performance to the cited predicate device.

7. Summary of Performance Data

- Mechanical testing was carried out as per ASTM F2077 and ASTM F2267: Static compression, static compression-shear, dynamic compression, dynamic compression-shear and subsidence.
- Packaging testing was carried out as per ISO 11607, parts 1 and 2 for terminallysterilized medical devices.
- Biocompatibility evaluation was conducted in accordance with FDA Guidance, Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process".
- Sterilization testing was conducted as per ISO 11137-1 and ISO11137-2.
- The reusable instruments are supplied non-sterile and are to be steam sterilized (to achieve SAL 10^{-6}) by the end user according to a validated process.

8. Conclusion of Substantial Equivalence

The subject Kleiner KG2 System has the same intended use/indications for use, the same or similar technology, comparable principles of operation, same range of size parameters, and same materials as the identified predicate systems:Ossous Aries-TC and Aries-TS (K181347), Stryker (K2M) Mojave (K193203), and NuVasive MLX (K173025). The Kleiner KG2 System does not present any new issues of safety or effectiveness as compared to the predicate systems. Performance testing demonstrates the subject implants are as strong or stronger compared to previously cleared devices with similar indications. Therefore, the Kleiner KG2 System is substantially equivalent to the identified predicate systems.