December 20, 2023

Kuros Biosciences B.V.
Hen Baron
Regulatory Affairs Manager
Professor Bronkhorstlaan 10, building 48
Bilthoven, Utrecht 3723MB
Netherlands

Re: K230736
Trade/Device Name: MagnetOs Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: November 21, 2023
Received: November 21, 2023

Dear Hen Baron:

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

Sara S. Thompson -S

For

Jesse Muir, PhD
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)*
K230736

Device Name
MagnetOs Putty

Indications for Use *(Describe)*
MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system i.e., the extremities, pelvis and posterolateral spine. MagnetOs Putty may be used standalone or mixed with autograft. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. MagnetOs Putty resorbs and is replaced with bone during the healing process.

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

Trade Name:	MagnetOs Putty
Manufacturer:	Kuros Biosciences B.V. Prof. Bronkhorstlaan 10, building 48, 3723 MB Bilthoven, The Netherlands
Submitter:	Scott Bruder, M.D., Ph.D. Founder and CEO Bruder Consulting & Venture Group (BCVG) Scott@BruderConsulting.com 201.874.9701
Contact:	Hen Baron, MSc. Regulatory Affairs Manager +31 (0)30 229 7280 Hen.Baron@kurosbio.com
Date Prepared:	December 19, 2023
Classifications:	Resorbable calcium salt bone void filler device
Class:	21 CFR 888.3045, Class II
Product Code:	MQV
Common Name:	Filler, bone void, calcium compound
Primary Predicate:	MagnetOs Granules (K213111)
Additional Predicates:	MagnetOs Putty (K181958) NuVasive AttraX Putty (K191974)

Indications For Use:

MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system *i.e., the extremities, pelvis and posterolateral spine*. MagnetOs Putty may be used standalone or mixed with autograft. These osseous defects may be surgically created or the result of traumatic injury to the bone and are not intrinsic to the stability of the bony structure. MagnetOs Putty resorbs and is replaced with bone during the healing process.

Device Description:

MagnetOs Putty is a synthetic, resorbable, osteoconductive bone void filler for the repair of bony defects. MagnetOs Putty consists of 65-75% Tri-Calcium Phosphate (TCP - $Ca_3(PO_4)_2$) and 25-35% Hydroxyapatite (HA - $Ca_{10}(PO_4)_6(OH)_2$) granules with a porous trabecular structure that resembles the interconnected porosity of human cancellous bone. The granules are covered with submicron-sized

features and are premixed with a synthetic polymeric binder. The biocompatible polymeric binder is composed of Poly L (Lactic Acid) (PLA) and Poly(Ethylene Glycol) (PEG) in a triblock polymer PLA-PEG-PLA; which consists of 10-20% PLA and 80-90% PEG.

The fast-resorbing polymeric binder in the subject device is designed to improve handling properties, as well as reduce the risk of granules migration. While the polymeric binder is rapidly resorbed after implantation, the granules in both devices guide the three-dimensional regeneration of bone in the defect site into which it is implanted.

When placed next to viable host bone, new bone will be deposited on the surface of the implant. The implant resorbs and is replaced by bone during the natural process of bone remodeling. MagnetOs Putty is a ready-for-use product. Pressure applied by manipulation allows the shaping of the devices to conform to the contours of bony defects. MagnetOs Putty is gamma-sterilized, comes in several sizes in block form and is sterile packaged for single use only.

This 510(k) expands the device's indications for use in K181958 as an autograft extender only to also allow use of the device alone in posterolateral spine.

Predicate Devices:

Kuros Biosciences submits the following information in this Premarket Notification to demonstrate that, for the purposes of FDA's regulation of medical devices, MagnetOs Putty is substantially equivalent in indications, design principles, and performance to the following predicate devices:

Primary Predicate:	MagnetOs Granules (K213111)
Additional Predicates:	MagnetOs Putty (K181958) NuVasive AttraX Putty (K191974)

Performance Testing Summary:

In support of the prior clearance of MagnetOs Putty (K181958), non-clinical testing data were submitted according to the "*Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device (issued June 2003)"*. Bench testing data including analytical characterization, chemical composition, physical properties and animal functional study were conducted for the subject MagnetOs Putty and the predicate devices. The results of the studies demonstrate substantial equivalence to the predicate devices.

Similar to the predicate MagnetOs Putty (K181958), the subject device is categorized as direct-patient contact with bone/tissue for permanent duration (>30 days). Biocompatibility was performed in accordance with "*ISO 10993-1, Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process"*.

MagnetOs Putty met the acceptance criteria for the Limulus amebocyte lysate (LAL) test, gel clot

method (Bacterial endotoxins test (BET)) per Ph.Eur. 2.6.14, Bacterial Endotoxins and USP <85>, Bacterial Endotoxins. MagnetOs Putty passed the Materials-Mediated Pyrogenicity Rabbit study per USP 39-NF34 and is marketed as "Non-Pyrogenic". A sterilization validation was performed and complies with ISO 11137, *"Sterilization of Sterilization of Health Care Products – Radiation"*, to ensure a sterility assurance level (SAL) of 10^{-6}. Product and sterile-barrier shelf-life studies were conducted per ISO 11607, "Packaging for terminally sterilized medical devices".

The performance of the MagnetOs Putty for standalone use was the same compared to the primary predicate MagnetOs Granules in posterolateral spinal fusion (PLF) animal model, was confirmed with a small clinical data set.

Substantial Equivalence:

The subject device, Primary Predicate device MagnetOs Granules (K213111), and Additional Predicate NuVasive AttraX Putty (K191974) have the same intended use, indications for use, product classification, and product code (MQV).

MagnetOs Putty's granular component is identical to Primary Predicate MagnetOs Granules (K213111), i.e. porous biphasic calcium phosphate granules with submicron-sized features. The subject device MagnetOs Putty is identical to the Additional Predicate MagnetOs Putty (K181958) in technological characteristics including materials, manufacturing process, with similar indications for use and therefore the biological evaluation conducted for the predicate MagnetOs Putty (K181958) is applicable to the subject device.

In vivo testing supported the substantial equivalence of MagnetOs Putty with Primary Predicate device MagnetOs Granules (K213111) for the expanded standalone use in posterolateral spine.

Conclusion:

The subject device and predicate devices have the same intended use, have similar technological characteristics, manufacturing process, and are made of similar materials. The data included in this submission demonstrate substantial equivalence to the predicate devices listed above. MagnetOs Putty is as safe, as effective, and performs as well as the predicate devices for the indications for use.