April 1, 2024

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

Re: K240442
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: February 2, 2024
Received: February 14, 2024

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,

Jesse Muir -S

Digitally signed by Jesse Muir -S
Date: 2024.04.01 09:18:59 -04'00'

Jesse Muir, Ph.D.
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: 07/31/2026
See PRA Statement below.

Submission Number *(if known)*

K240442

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, intervertebral disc space, and posterolateral spine. 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 may be used standalone or mixed with autograft. When used in intervertebral body fusion procedures, MagnetOs Putty must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler. 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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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary

Trade Name:	MagnetOs Putty
Manufacturer:	Kuros Biosciences B.V. Prof. Bronkhorstlaan 10, building 48, 3723 MB Bilthoven, The Netherlands +31 (0)30 229 7280
Contact:	Hen Baron, MSc Regulatory Affairs Manager Prof. Bronkhorstlaan 10, building 48, 3723 MB Bilthoven, The Netherlands Office: +31 (0)30 229 7280 hen.baron@kurosbio.com
Prepared by:	MCRA, LLC 803 7th Street, NW, 3rd Floor Washington, DC 20001 Office: 202.552.5800
Date Prepared:	March 20, 2024
Classifications:	**21 CFR 888.3045**
Class:	II
Product Codes:	MQV
Primary Predicate:	NuVasive Attrax Putty, NuVasive, Inc., K203714
Additional Predicate:	MagnetOs Putty, Kuros Biosciences B.V, K230736

Indications For Use:

MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system, *i.e., the extremities, pelvis, intervertebral disc space, and posterolateral spine*. 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 may be used standalone or mixed with autograft. When used in intervertebral body fusion procedures, MagnetOs Putty must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler. 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 surface of the granules in MagnetOs Putty is covered with needle-shaped features that are submicron in size. The granules 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 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.

MagnetOs Putty is MRI (Magnetic Resonance Imaging) Safe.

Predicate Device:
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: NuVasive Attrax Putty, NuVasive, Inc., K203714
Additional Predicate: MagnetOs Putty, Kuros Biosciences B.V, K230736

Performance Testing Summary:
The purpose of this submission is to expand the indications for use of the MagnetOs Putty device to include use in the intervertebral disc space in conjunction with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

In support of the prior clearance (K230736), non-clinical testing data, supplemented with clinical data, were submitted according to the guidance documents *Guidance for Industry and FDA Staff - Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device* (issued June 2003) and *Submission and Review of Sterility Information in Premarket Notification (510(k)) Submissions for Devices Labeled as Sterile* (issued January 2016). The non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included analytical characterization, chemical composition, physical properties, and animal functional studies.

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"*.

In-vitro studies showed that MagnetOs Putty induced the growth of a bone-like apatite layer on the surface of the MagnetOs Granules component following exposure to simulated body fluid.

The performance testing and supporting rationale are further detailed in the "Performance Testing" Section of the subject submission.

Substantial Equivalence:
The subject device was demonstrated to be substantially equivalent to the NuVasive Attrax Putty (K203714) primary predicate device with respect to indications, design principles, and performance.

The subject device and primary predicate device both perform their intended use via calcium phosphate materials and are provided as putties in multiple dosages. The subject and primary predicate devices are provided sterile and are intended for single-patient and single-use.

The subject device is identical to the reference device (MagnetOs Putty, K230736). The performance of the reference device has previously been assessed at the time of the prior clearance.

Non-clinical testing data and animal testing data, supplemented with a clinical rationale, are referenced to demonstrate the performance of the subject device is substantially equivalent to that of the predicate device.

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues or concerns of safety or efficacy.

Conclusion:
The subject device and the predicate devices have the same intended use, have similar technological characteristics, and are made of similar materials. The subject and predicate devices are packaged in similar materials and are sterilized using similar methods. 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.