January 10, 2022

Kuros Biosciences B.V.
% Mehdi Kazemzadeh-Narbat
Associate Director, Regulatory Affairs
MCRA, LLC
1050 K Street NW, Suite 1000
Washington, District of Columbia 20001

Re: K213111
Trade/Device Name: MagnetOs granules
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: December 9, 2021
Received: December 9, 2021

Dear Mehdi Kazemzadeh-Narbat:

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

Laura C. Rose, 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*

K213111

Device Name
MagnetOs Granules

Indications for Use *(Describe)*

MagnetOs Granules is an implant intended to fill bony voids or gaps of the skeletal system, i.e., the extremities, pelvis and posterolateral spine. MagnetOs Granules may be used standalone or mixed with autograft, blood, and/or bone marrow. 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 Granules 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

Device Trade Name:	MagnetOs Granules
Manufacturer:	Kuros Biosciences B.V. Prof. Bronkhorstlaan 10, building 48, 3723 MB Bilthoven, The Netherlands
Contact:	Sonja van der Meer, BSc Regulatory Affairs Expert +31 (0)30 229 7280
Prepared by:	Mehdi Kazemzadeh-Narbat, PhD, PMP, CQA Associate Director, Regulatory Affairs, MCRA, LLC 1050 K Street NW, Suite 1000 Washington, DC 20001 Office: 202.552.6011 mkazemzadeh@mcra.com
Date Prepared:	January 10, 2022
Classifications:	Resorbable calcium salt bone void filler device
Class:	21 CFR 888.3045, Class II
Product Code:	MQV
Primary Predicate:	NuVasive AttraX Putty (K191974)
Additional Predicates:	MagnetOs Granules (K161859) MagnetOs Putty (K181958) Actifuse Bone graft Substitute (K082575) Synthes ChronOS (K043045)

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Indications For Use:

MagnetOs Granules is an implant intended to fill bony voids or gaps of the skeletal system, *i.e., the extremities, pelvis and posterolateral spine*. MagnetOs Granules may be used standalone or mixed with autograft, blood, and/or bone marrow. 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 Granules resorbs and is replaced with bone during the healing process.

Device Description:

MagnetOs Granules is a synthetic, resorbable, osteoconductive bone void filler for the repair of bony defects. MagnetOs Granules 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. MagnetOs Granules guide the three-dimensional regeneration of bone in the defect site into which it is implanted. New bone will be deposited on the surface of the graft when placed next to viable host bone. The graft resorbs and is replaced by bone during the natural process of bone remodeling. MagnetOs Granules is a ready-to-use product. MagnetOs Granules is provided in vials in a range of product volumes. MagnetOs Granules is gamma-sterilized and sterile packaged for single use only.

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 Granules is substantially equivalent in indications, design principles, and performance to the following predicate devices, which have been determined by FDA to be substantially equivalent to pre-amendment devices:

Primary Predicate:	NuVasive AttraX Putty (K191974)
Additional Predicates:	MagnetOs Granules (K161859)
	MagnetOs Putty (K181958)
	Actifuse Bone graft Substitute (K082575)

Performance Testing Summary:
Bench testing data including analytical characterization, chemical composition, physical properties and animal functional study were conducted for the subject MagnetOs Granules and the predicate devices. The results of the study demonstrate substantial equivalence to the predicate devices.

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The MagnetOs Granules met the acceptance criteria for Bacterial endotoxins test (BET)) Limulus amebocyte lysate (LAL) and passed the Materials-Mediated Pyrogenicity Rabbit study and is marketed as "Non-Pyrogenic".

In addition, MagnetOs Granules was clinically evaluated in instrumented thoracolumbar posterolateral fusion in a randomized non-inferiority, multicenter, observer blinded, intra-patient-controlled trial. The objective of the study was to evaluate whether MagnetOs Granules used alone as a bone void filler is non-inferior to autologous bone graft (iliac crest + local bone) in instrumented posterolateral fusion by means of an intra-patient model where each patient received MagnetOs Granules on one side of the posterolateral fusion and autograft on the other side of the posterolateral fusion. The clinical evidence from this randomized and intra-patient controlled trial demonstrates the non-inferiority of MagnetOs Granules versus autologous bone graft in instrumented posterolateral spinal fusion.

Substantial Equivalence:
The subject device and primary predicate device NuVasive AttraX Putty (K191974) have the same intended use, the same product classification and product code (MQV) and have similar Indications for Use.

The subject device MagnetOs Granules is identical to the cleared predicate MagnetOs Granules (K161859) in technological characteristics including materials, manufacturing process, with similar indications for use, the biological evaluation conducted for the predicate MagnetOs Granules (K161859) is applicable to the subject device and there is no need for further biocompatibility testing.

Similar to K161859, the subject device is categorized as direct-patient contact with bone/ tissue for permanent duration (>30 days). Since the subject device is identical to the predicate device

The modifications between the subject device and K161859 is limited to the expansion of Indications for Use of the MagnetOs Granules to include possibility of *stand-alone* use in *extremities, pelvis,* and *posterolateral spine.*

To support the performance of the MagnetOs Granules in combination with blood and BMA, a critical sized femoral defect rabbit model was conducted on the MagnetOs Granules alone, MagnetOs Granules combined with BMA, and MagnetOs Granules combined with blood to demonstrate substantial equivalence performance with the predicates MagnetOs Putty (K181958), and Actifuse Bone graft Substitute (K082575).

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