May 23, 2025

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

Re: K243474
Trade/Device Name: MagnetOs MIS
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: May 7, 2025
Received: May 7, 2025

Dear Ms. 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.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

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: 2025.05.23 10:17:06 -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)*

K243747

Device Name

MagnetOs MIS

Indications for Use *(Describe)*

MagnetOs MIS is intended to fill bony voids or gaps of the skeletal system, i.e., the extremities, pelvis, intervertebral disc space, and posterolateral spine. The 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. In the extremities, pelvis, intervertebral disc space and posterolateral spine, MagnetOs MIS may be used standalone or with autograft as a bone extender. When used in intervertebral body fusion procedures, MagnetOs MIS must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
MagnetOs MIS 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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K243474

510(k) Summary

Manufacturer	Kuros Biosciences B.V. Prof. Bronkhorstlaan 10, building 48 3723 MB Bilthoven The Netherlands
Contact	Hen Baron Regulatory Affairs Manager Office: +31 (0)30 229 7280 hen.baron@kurosbio.com
Date Prepared	May 15, 2025
Trade Name	MagnetOs MIS
Common Name	Bone void filler
Classification	Resorbable calcium salt bone void filler device
Class	21 CFR 888.3045, Class II
Product Code	MQV
Primary Predicate	NovaBone Putty MIS, NovaBone Products LLC (K242299)
Additional Predicates	MagnetOs Easypack Putty, Kuros Biosciences B.V. (K241212) MagnetOs Putty, Kuros Biosciences B.V. (K240442)

Indications for Use

MagnetOs MIS is intended to fill bony voids or gaps of the skeletal system, i.e., the extremities, pelvis, intervertebral disc space, and posterolateral spine. The 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. In the extremities, pelvis, intervertebral disc space and posterolateral spine, MagnetOs MIS may be used standalone or with autograft as a bone extender. When used in intervertebral body fusion procedures, MagnetOs MIS must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
MagnetOs MIS resorbs and is replaced with bone during the healing process.

Device Description

MagnetOs MIS includes a synthetic, resorbable, osteoconductive bone void filler for the repair of bony defects. MagnetOs MIS graft material is a mixture of ceramic granules premixed with a synthetic polymeric binder that provides cohesion between the granules. The ceramic portion of MagnetOs MIS 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.
While the polymeric binder is rapidly resorbed after implantation, the granules of MagnetOs MIS 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 MIS graft material is provided in a 5cc pre-filled cartridge, packed together with a delivery system kit in a ready-to-use format. The MagnetOs MIS delivery system allows users to apply the bone graft into the defect. MagnetOs MIS is gamma-sterilized and sterile packaged for single use only.

Substantial Equivalence

This submission includes the addition of MagnetOs MIS configuration to MagnetOs synthetic bone void filler products. The subject device, MagnetOs MIS, shares the same intended use and indications for use as the primary predicate NovaBone Putty and additional predicate devices MagnetOs Easypack Putty and MagnetOs Putty.

The delivery system kit of the subject device, including the pre-filled cartridge, has identical design principles and material compositions as the primary predicate. The graft material in the subject device is similar to that of the primary predicate, as both contain granules pre-mixed with a resorbable, synthetic polymeric binder.

The ceramic granules in the subject device's graft material are identical in size and composition to those in the additional predicate devices, MagnetOs Easypack Putty and MagnetOs Putty. The polymeric binder is identical to MagnetOs Easypack Putty.

It has been demonstrated that the minor differences in technological characteristics between the subject device and predicate devices do not raise different questions of safety and effectiveness and that MagnetOs MIS is substantially equivalent to the predicate devices.

Performance

Bench testing data and biocompatibility data was provided to address the differences in technological characteristics between subject device and primary predicate and to assess the ability of the MagnetOs MIS delivery system to deliver the graft material into the bone defect. MagnetOs MIS 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.

Packaging testing was conducted per ASTM F2096 (Gross bubble leak) and ASTM F88 (Seal strength). The results demonstrate the packaging integrity, stability and performance until point of use.

No additional animal performance or clinical data was provided to support substantial equivalence for the proposed indications. Instead, animal and clinical data from previous clearances of the additional predicate devices were leveraged to support the current submission, as recommended in the FDA's *Class II Special Controls Guidance document for Resorbable Calcium Salt Bone Void Filler Devices.*

Summary

The subject device and predicates have the same intended use and indications for use. Any differences in technological characteristics between the subject device and predicate devices do not raise different questions of safety and effectiveness. Based on the data presented in this 510(k) submission, the device is substantially equivalent to the predicate devices.