June 27, 2024

Kuros Biosciences
% Scott Bruder, MD, PhD
Founder and CEO
Bruder Consulting & Venture Group
268 Glen Place
Franklin Lakes, New Jersey 07417

Re: K241212
Trade/Device Name: MagnetOs Easypack Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: April 29, 2024
Received: April 30, 2024

Dear Dr. Bruder:

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,

Robert M. Stefani -S

Digitally signed by Robert M. Stefani -S
Date: 2024.06.27 13:20:54 -04'00'

For: 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)*

K241212

Device Name

MagnetOs Easypack Putty

Indications for Use *(Describe)*

MagnetOs Easypack Putty 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 Easypack Putty may be used standalone or with autograft as a bone extender. When used in intervertebral body fusion procedures, MagnetOs Easypack Putty must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.
MagnetOs Easypack 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.

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Kuros Biosciences

510(k) Summary

Trade Name:	MagnetOs Easypack 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:	June 26, 2024
Classification:	Resorbable calcium salt bone void filler device
Common Name	Bone void filler
Class:	21 CFR 888.3045, Class II
Product Code:	MQV
Primary Predicate:	SIGNAFUSE Putty (K233490)
Additional Predicates:	MagnetOs Putty (K240442) MagnetOs Easypack Putty (K233607) MagnetOs Granules (K232347)

Indications For Use:

MagnetOs Easypack Putty 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 Easypack Putty may be used standalone or with autograft as a bone extender. When used in intervertebral body fusion procedures, MagnetOs Easypack Putty must also be used with an intervertebral body fusion device cleared by FDA for use with a bone void filler.

MagnetOs Easypack Putty resorbs and is replaced with bone during the healing process.

Device Description:

MagnetOs Easypack Putty is a synthetic, resorbable, osteoconductive bone void filler for the repair of bony defects. MagnetOs Easypack 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. 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 Easypack 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 Easypack Putty is gamma-sterilized, comes in several sizes in block form and is sterile packaged for single use only.

Substantial Equivalence:

MagnetOs Easypack Putty is substantially equivalent in indications, design principles, and performance to the following predicate devices:

Primary Predicate:	SIGNAFUSE Putty (K233490)
Additional Predicates:	MagnetOs Putty (K240442)
	MagnetOs Easypack Putty (K233607)
	MagnetOs Granules (K232347)

This submission consolidates the subject device's indications across the MagnetOs Family of products to include use as an autograft extender and for standalone use without autograft mixing, the same as the Primary Predicate SIGNAFUSE (K233490). The subject device, MagnetOs Easypack Putty (K233607) and Primary Predicate SIGNAFUSE (K233490) have the same intended use, product classification, and product code (MQV). The subject device and predicates are all intended to resorb and be replaced by new bone, and are indicated for use in extremities, pelvis, intervertebral disc space, and posterolateral spine, except for K233607 which is only cleared for use in spine indications.

MagnetOs Easypack Putty's is similar to the Primary Predicate SIGNAFUSE Putty (K233490), both of which are composed of granules in a resorbable binder. MagnetOs Easypack Putty and SIGNAFUSE Putty differ with respect to the composition of the granules and binder: MagnetOs Easypack Putty consists of biphasic calcium phosphate granules in a synthetic polymer binder, whereas SIGNAFUSE Putty consists of biphasic calcium phosphate and bioactive glass granules in an alkylene oxide polymer.

MagnetOs Easypack Putty's granular component is identical to Additional Predicate MagnetOs Granules (K232347), i.e. porous biphasic calcium phosphate granules with submicron-sized features. The subject device MagnetOs Easypack Putty is identical to the Additional Predicate MagnetOs Easypack Putty (K233607) in technological characteristics including materials, manufacturing process,

Performance Testing Summary:

MagnetOs Easypack Putty (K233607) has addressed non-clinical special controls following FDA's "*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 Easypack Putty. The results of the studies demonstrate substantial equivalence to the predicate devices.

Consistent with additional predicate MagnetOs Easypack Putty (K233607), the subject device is categorized as direct-patient contact with bone/tissue for permanent duration (>30 days). Biocompatibility was addressed in accordance with FDA's Guidance, *"Use of International Standard ISO 10993-1, "Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process""*.

MagnetOs Easypack 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 Easypack 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 Easypack Putty device for standalone use in interbody fusion was established with clinical data. The primary endpoint was fusion-based imaging assessment, and was determined to be substantially equivalent. The performance of MagnetOs Easypack Putty device for use in extremities, pelvis, and posterolateral spine was established based on animal performance data from MagnetOs Easypack Putty (K233607, K211201), MagnetOs Putty (K240442, K181958), and MagnetOs Granules (K232347) and clinical performance data from MagnetOs Putty (K233607, K230736) and MagnetOs Granules (K232347, K230736).

The clinical performance data was provided in this submission to support the indications for use. The clinical data was obtained from a retrospective review of 20 patients previously treated with the MagnetOs Easypack Putty in interbody fusion as standalone without any autograft mixing. The primary endpoint was radiographic fusion at 12 months, which was compared to literature including the primary predicate.

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 the submission demonstrate substantial equivalence to the predicate devices listed above. MagnetOs Easypack Putty is as safe, as effective, and performs as well as the predicate devices for the indications for use.