September 2, 2021

Kuros Biosciences B.V.
℅ Angela Paterson
Senior Consultant
Compliance Solutions Ltd
Suite 10, Dunswood House, 1 Dunswood Road, Cumbernauld
Glasgow G67 3EN
United Kingdom

Re: K211201
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: July 28, 2021
Received: August 3, 2021

Dear Angela Paterson:

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,

Laura C. Rose, Ph.D.
Assistant Director
DHT6C: Division 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)*
K211201

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. posterolateral spine. In the posterolateral spine, MagnetOs Easypack Putty must be used with autograft as a bone graft extender. 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.

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
Traditional 510(k)
For MagnetOs Easypack Putty

510(k) Summary

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:

Kuros Biosciences B.V.

Submitter's Address:

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The Netherlands

Establishment Registration Number:

3008147766

Contact Person:

Angela Paterson

Telephone + 44 7884 274 220

Date Prepared:

2nd September 2021

The Device Classification Information regarding MagnetOs Easypack Putty is summarized below.

Primary Product Code:

Regulation Number	Device	Device Class	Product Code	Classification Panel
888.3045	Resorbable calcium salt bone void filler	2	MQV	Orthopedic

Device Trade Name:

MagnetOs Easypack Putty

Device Common Name:

MagnetOs Easypack Putty

Intended Use:

MagnetOs Easypack Putty is intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. In the posterolateral spine, MagnetOs Easypack Putty must be used with autograft as a bone graft extender. 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.

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

Summary of Substantial Equivalence:

MagnetOs Easypack Putty is substantially equivalent in indications and design principles to the following cleared and legally marketed predicate devices:

- MagnetOs Putty (K181958, K171563), the primary predicate, is highly similar to the subject device used for the comparison animal spine study. It consists of the identical unmodified MagnetOs granules component, which is responsible for the mode of action of the subject device, together with a synthetic polymeric binder, which is highly similar to the binder used in the subject device.

- Osteo^3 ZP Putty (K193075) is packed in identical primary packaging and is indicated for the same intended use as MagnetOs Easypack Putty.

- Actifuse ABX (K082575) is packed in comparable primary packaging and has similar indications for use, as a bone void filler in spine.

- MagnetOs Granules (Xpand Biotechnology B.V., K161859) is cleared for the same intended use as MagnetOs Easypack Putty. Identical MagnetOs granules are present in MagnetOs Easypack Putty and MagnetOs Putty.

  Note: *Xpand Biotechnology B.V. is the previous company name of Kuros Biosciences B.V.*

The subject device, MagnetOs Easypack Putty, and predicate devices MagnetOs Putty, Osteo^3 ZP Putty, Actifuse ABX, and MagnetOs Granules have the same intended use, the same product classification and product code (MQV) and have similar Indications for Use.

Property	510(k) Subject Device	Primary Predicate Device	Equivalent Device	Equivalent Device	Equivalent Device
Device Name	MagnetOs Easypack Putty	MagnetOs Putty	Osteo^3 ZP Putty	Actifuse ABX	MagnetOs Granules
Device Manufacturer	Kuros Biosciences B.V.	Kuros Biosciences B.V.	SIRAKOSS Ltd.	Baxter	Kuros Biosciences B.V.
510(k)	No	K181958, K171563	K193075	K082575	K161859
Device Classification	II	II	II	II	II
Product Code	MQV	MQV	MQV	MQV	MQV
Use Environment	Medical/ Clinical	Medical/ Clinical	Medical/ Clinical	Medical/ Clinical	Medical/ Clinical

MagnetOs Easypack Putty is substantially equivalent to the predicate devices MagnetOs Putty, Osteo^3 ZP Putty, Actifuse ABX, and MagnetOs Granules with respect to design, structure, materials, and mechanism of action, and has similar Indications for Use in posterolateral spine. MagnetOs Putty is the primary predicate device used for animal performance testing studies.

For the three MagnetOs devices, the MagnetOs granules component is identical.

Between the MagnetOs Easypack Putty subject device and the MagnetOs Putty, Osteo^3 ZP Putty, Actifuse ABX, and MagnetOs Granules predicate devices, there are limited differences. These aspects do not affect the safety and biocompatibility of MagnetOs Easypack Putty because of the identical nature of the building blocks of these materials and the site of application (bone).

The subject device and the Osteo^3 ZP Putty and Actifuse ABX predicate devices are provided in equivalent primary packaging (open-ended syringes).

The granules used in MagnetOs Easypack Putty subject device are identical to the granules used in the MagnetOs Putty primary predicate device. The polymeric binders in these two devices share the same identity. The only difference between the two binders is the slightly different molecular weight to adjust softness. The nature and essential characteristics of the granules remain unaltered when mixed with the polymeric binder.

As a result, MagnetOs Easypack Putty, and all predicate devices, including MagnetOs Granules (which consist of granules alone, without a binder/carrier), are equivalent in terms of mechanism of action (same fundamental technology): they all provide calcium salt bone void fillers which resorb and are replaced by bone during the natural process of bone healing. All devices have equivalent Indications for Use.

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, premixed with a synthetic polymeric binder that provides cohesion between the granules.

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 Easypack Putty is a ready-to-use product. Pressure applied by manipulation allows users to shape MagnetOs Easypack Putty to conform to the contours of bony defects.

MagnetOs Easypack Putty is provided in open-ended syringes in a range of product volumes. MagnetOs Easypack Putty is gamma-sterilized and sterile packaged for single use only.

Technological Characteristics:

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, biocompatibility, and performance characteristics in accordance with FDA recognized consensus standards and FDA guidance documents as applicable.

Non-Clinical Tests (Performance/Physical Data):

Non-clinical testing 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 chemical composition, physical properties, sterilization, material-mediated pyrogenicity, sterile barrier shelf life, product shelf life, and biocompatibility.

Bacterial endotoxin testing of MagnetOs Easypack Putty was conducted and met endotoxin limits.

Bench testing and animal data demonstrated that the safety and effectiveness of the MagnetOs Easypack Putty is equivalent to the predicate devices. A summary is given below.

Testing was performed to evaluate the physicochemical and crystallographic characteristics of MagnetOs Putty. Characterization tests included:

- Product visual inspection
- Composition, crystallinity, and Ca/P ratio (X-ray diffraction (XRD))
- Microstructure (SEM)
- Identity (Fourier Transform Infrared (FTIR) spectroscopy)
- Porosity (mercury intrusion porosimetry)
- Polymer inherent viscosity (Ubbelohde Viscometry)
- Polymer chemical composition (NMR)
- Organic volatile impurities (OVI)
- Water content (Coulometric Karl Fischer Titration)
- Trace elemental analysis (ICP-MS)
- In vitro dissolution and pH
- Polymer irrigation test
- Calcium ion release (ICP-MS)

Biocompatibility Testing

Biocompatibility of the subject device was assessed using the methodology described in ISO 10993-1, ISO 10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO10993-11, ISO 10993-12, ISO 10993-18, USP <87>, USO <88>, USP 43 – NF 38 and European Pharmacopeia, 10th edition, 2020.

Animal Studies

MagnetOs Putty is the primary predicate device used for animal performance testing studies. The performance of the MagnetOs Easypack Putty was established in a posterolateral spine fusion animal model justifying that MagnetOs Easypack Putty can be used as an autograft extender (1:1) in posterolateral spine.

Animal testing was performed in a rabbit posterolateral spine fusion model to demonstrate substantial equivalence to the primary predicate device (K181958, K171563). Animals were evaluated after implantation with the subject device, the primary predicate device, and autograft (positive control) up to 12 weeks. Evaluation endpoints included manual palpation, range of motion/flexibility testing, plain and high-resolution radiography, micro-computed tomography (micro-CT) imaging, undecalcified histologic evaluation, and histomorphometric analysis.

Decalcified paraffin histology sections also were graded according to ISO 10993-6 (Annex E).

Clinical Studies

No clinical studies were conducted to prove substantial equivalence as part of the submission.

Safety and Effectiveness/Conclusion:

Based on the information presented in this 510(k) premarket notification, MagnetOs Easypack Putty is considered substantially equivalent to predicate devices. MagnetOs Easypack Putty is as safe and effective as currently marketed predicate devices.

It is our determination that the MagnetOs Easypack Putty is as safe, as effective and performs within its design specifications, and is substantially equivalent to predicate devices.