April 14, 2022

Kuros Biosciences BV
Sonja van der Meer
Regulatory Affairs Expert
Professor Bronkhorstlaan 10, Building 48
Bilthoven, 3723 MB,
The Netherlands

Re: K213959
Trade/Device Name: MagnetOs Flex Matrix
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable Calcium Salt Bone Void Filler Device
Regulatory Class: Class II
Product Code: MQV
Dated: March 9, 2022
Received: March 9, 2022

Dear Sonja van der Meer:

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 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)*
K213959

Device Name
MagnetOs Flex Matrix

Indications for Use *(Describe)*
MagnetOs Flex Matrix is intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. In the posterolateral spine, MagnetOs Flex Matrix must be hydrated with bone marrow aspirate and used as an extender to autograft bone. 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 Flex Matrix 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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

Kuros Biosciences
Traditional 510(k)
For MagnetOs Flex Matrix

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:

Kuros Biosciences B.V.
Prof. Bronkhorstlaan 10, building 48
3723 MB Bilthoven
The Netherlands

Establishment Registration Number:

3008147766

Contact Person:

Sonja van der Meer

Telephone +31 (0)30 229 7280

Date Prepared:

14th April 2022

Kuros Biosciences
Traditional 510(k)
For MagnetOs Flex Matrix

The Device Classification Information regarding MagnetOs Flex Matrix 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 Flex Matrix

Device Common Name

Resorbable calcium salt bone void filler

Device Description

MagnetOs Flex Matrix is a resorbable, osteoconductive bone void filler, intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. In the posterolateral spine, MagnetOs Flex Matrix must be hydrated with bone marrow aspirate and used as an extender to autograft bone. The product is biocompatible.

MagnetOs Flex Matrix is a mixture of medical grade collagen and hydroxyapatite and β-tricalcium phosphate ceramic granules. The collagen is produced from highly purified bioresorbable bovine split skin and consists mainly of collagen type I. The ceramic portion of MagnetOs Flex Matrix consists of β-tricalcium phosphate and hydroxyapatite.

MagnetOs Granules has a porous trabecular structure that resembles the structure and interconnected porosity of human cancellous bone. The surface of MagnetOs Granules is covered with needle-shaped features that are submicron in size.

The collagen matrix has a fibrillar porous structure which allows for the exposure of MagnetOs Granules' surface structure without interfering with its mode of action. While the collagen sponge matrix is readily resorbed in the first 6 weeks after implantation, MagnetOs Granules guides the three-dimensional regeneration of bone in the defect into which it is implanted. New bone will be deposited on the surface of the graft when it is placed next to viable host bone. The graft will be resorbed and replaced by bone during the natural process of bone remodelling.

MagnetOs Flex Matrix is a ready-to-use product. Upon hydration, the material is moldable and allows users to shape MagnetOs Flex Matrix to conform to the contours of bony defects. MagnetOs Flex Matrix is gamma-sterilized, sterile packaged and ready for single patient use only.

Intended Use

MagnetOs Flex Matrix is intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. In the posterolateral spine, MagnetOs Flex Matrix must be hydrated with bone marrow aspirate and used as an extender to autograft bone. The osseous defects may be surgically created or the result of traumatic injury to the bone that are not intrinsic to the stability of the bony structure.

MagnetOs Flex Matrix resorbs and is replaced with bone during the healing process.

Summary of Substantial Equivalence

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

Table 1.1: Subject device and Predicate devices general information

Property	510(k) Subject Device	Primary Predicate Device	Equivalent Device	Equivalent Device
Device Name	MagnetOs Flex Matrix	MASTERGRAFT® Strip	Vitoss Scaffold Foam	MagnetOs Granules
Device Manufacturer	Kuros Biosciences B.V.	Medtronic Sofamor Danek USA	Othovia, Inc	Kuros Biosciences B.V.
510(k)	No	K082166	K032288	K161859
Device Classification	II	II	II	II
Product Code	MQV	MQV	MQV	MQV
Use Environment	Medical / Clinical	Medical / Clinical	Medical / Clinical	Medical / Clinical
Anatomic location	Bony voids or gaps of the skeletal system, i.e., posterolateral spine	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis	Bony voids or gaps of the skeletal system, i.e., the extremities, spine and pelvis	Bony voids or gaps of the skeletal system, i.e., posterolateral spine
Materials	hydroxyapatite and β-tricalcium phosphate mixture	hydroxyapatite and β-tricalcium phosphate mixture	β-tricalcium phosphate	hydroxyapatite and β-tricalcium phosphate mixture
	Bovine collagen type I	Bovine collagen type I	Bovine collagen type I	-
Dosage form	Strips	Strips	Strips	Granules

MagnetOs Flex Matrix is substantially equivalent to the predicate device MASTERGRAFT® Strip and to equivalent devices Vitoss Foam and MagnetOs Granules with respect to design, structure, materials, and mechanism of action, and has similar Indications for Use.

For the two MagnetOs devices, the MagnetOs Granules component is identical.

MASTERGRAFT® Strip is the primary predicate device used for animal performance testing studies. MagnetOs Granules is the reference standard comparators used for comparison animal studies.

Non-clinical Testing (Performance/Physical Data):

Characterization of MagnetOs Flex Matrix materials has been conducted in compliance with the Guidance for Industry and FDA Staff – Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device (Document issued on: June 2, 2003) and the requirements of other applicable standards.

Bench-top testing was performed to evaluate the physicochemical and crystallographic characteristics of MagnetOs Flex Matrix, which demonstrated that the MagnetOs Granules component in MagnetOs Flex Matrix is identical to MagnetOs Granules device. With SEM and XRD it is confirmed that the collagen matrix does not change the MagnetOs Granules specifications. This ensures that the mode of action is not compromised.

Biocompatibility testing:
The biocompatibility of the MagnetOs Flex Matrix is demonstrated by ISO 10993 testing and the long history of clinical use of the collagen and calcium phosphate materials for the same intended use.

Bacterial endotoxin testing was performed using the limulus amebocyte lysate (LAL) method and showed that the device meets the endotoxin limits of established guidelines.

Animal studies:
Substantial equivalence in performance of MagnetOs Flex Matrix to Mastergraft Strip was provided by in vivo animal data in the intended use.

Mastergraft Strip is the primary predicate device used for animal performance testing studies. The performance of the MagnetOs Flex Matrix was established in a posterolateral spine fusion animal model that justifies that MagnetOs Flex Matrix can be used as an autograft extender (1:1 volume ratio) in posterolateral spine.

Animal testing was performed in a rabbit posterolateral spine fusion model to demonstrate substantial equivalence to the primary predicate device. 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).

The exact same animal model and study design were used for pre-clinical performance testing of MagnetOs Granules (K161859, K213111). By comparing the outcomes of both studies, substantial equivalence in performance of MagnetOs Flex Matrix and MagnetOs Granules is confirmed.

From all available pre-clinical data, it is concluded that the performance of MagnetOs Flex Matrix is substantially equivalent to both the primary predicate device, Mastergraft Strip, and MagnetOs Granules.

Safety and Effectiveness/Conclusion:

Based on the information presented in these 510(k) premarket notifications, MagnetOs Flex Matrix is considered substantially equivalent to predicate devices. It is our determination that MagnetOs Flex Matrix is as safe and effective as currently marketed predicate devices.