DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

August 24, 2017

Kuros Biosciences B.V.
Ms. Yvonne P. Bovell
QA/RA Manager
Professor Bronkhorstlaan 10, Building 48
Bilthoven, 3723MB
The Netherlands

Re: K171563
Trade/Device Name: MagnetOs Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: May 23, 2017
Received: May 30, 2017

Dear Ms. Bovell:

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. 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); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K171563

Device Name

MagnetOs Putty

Indications for Use *(Describe)*

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

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."

510(k) Summary MagnetOs Putty

Date: 09Aug17

ADMINISTRATIVE INFORMATION

Submitter details:

Name	Kuros Biosciences B.V.
Address	Professor Bronkhorstlaan 10, building 48 3723 MB Bilthoven The Netherlands
Telephone	+31-30-2297280
Fax	+31-30-2297299

Contact person:

Name	Yvonne P. Bovell
Position	QA/RA Manager
Telephone	+31-30-2297212
Email	yvonne.bovell@signifix.com

DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	MagnetOs Putty
Classification Name	Resorbable calcium salt bone void filler device
Classification Regulations	21 CFR 888.3045, Class II
Product Code	MQV
Classification Panel	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch	Restorative Devices Branch

INDICATIONS FOR USE

MagnetOs Putty is an implant intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. MagnetOs Putty must be used with autograft as a bone graft extender in the posterolateral spine. 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 Putty resorbs and is replaced with bone during the healing process.

DEVICE DESCRIPTION

MagnetOs Putty is a synthetic, resorbable and osteoconductive bone void filler for the repair of bony defects, containing 65-75% Tri-Calcium Phosphate (TCP, $Ca_3(PO_4)_2$) and 25-35% Hydroxyapatite (HA, $Ca_5(PO_4)_3OH$) granules, premixed with a synthetic polymeric binder that provides cohesion between the granules.

MagnetOs Putty is gamma-sterilized, comes in four sizes in block form and is sterile packaged for single use only.

EQUIVALENCE TO MARKETED DEVICE

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

- Xpand Biotechnology B.V., MagnetOs (granules), cleared under K161859;

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

- Progentix Orthobiology B.V., AttraX Putty, cleared under K151584;
- Biostructures LLC, Signafuse Bioactive Bone Graft Putty; cleared under K132071;
- Synthes; chronOS Composite; cleared under K071046.

The subject device and predicate devices K161859, K151584, K132071, and K071046 have the same intended use, the same product classification and product code (MQV), and have similar Indications for Use.

MagnetOs Putty is substantially equivalent to the predicate MagnetOs Granules (K161859). MagnetOs Putty consists of the identical MagnetOs ceramic granules cleared under K161859 which are therefore equivalent with respect to design, structure, materials, manufacturer, methods of production and testing, mechanism of action, and Indications for Use in the posterolateral spine. The only difference between the two devices is that MagnetOs Putty has the granules premixed with a rapidly resorbing polymeric binder (LEOL) that acts as a temporary binder for the granules to facilitate handling and has no effect on device functionality after *in vivo* implantation.

The LEOL binder is a PLA-PEG-PLA that resorbs rapidly after implantation into PEG and PLA components. These components have a known history of use in binder formulation for ceramic granules in the predicate devices: AttraX Putty (K151584); Bioactive Bone Graft Putty (K132071), and ChronOS Composite (K071046), all bone void fillers with Indication for use similar to those of MagnetOs Putty.

The LEOL binder material is rapidly resorbed after implantation, allowing for osteoconductive bone growth on the granules. As a result, MagnetOs Putty and the predicate MagnetOs Granules are equivalent in term of mechanism of action (same fundamental technology): they both provide the same osteoconductive calcium salt bone

void filler which resorbs and is replaced by bone during the natural process of bone healing. Both devices have equivalent Indications for Use.

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.

Biocompatibility of the device was assessed using the methodology described in ISO 10993-1, ISO10993-3, ISO 10993-5, ISO 10993-6, ISO 10993-10, ISO10993-11 and USP <151>.

Material characterization performed included the following:

- chemical composition was analyzed by x-ray diffraction (XRD), and Fourier transform infrared spectroscopy (FTIR), Nuclear Magnetic Resonance (NMR), Organic Volatile Impurities (OVI)
- trace elemental analysis was performed by inductively coupled plasma/mass spectroscopy (ICP/MS),
- surface microstructure and bioactivity were evaluated by scanning electron microscopy (SEM) and in vitro surface mineralization study (following immersion in simulated body fluid (SBF)), and
- physical properties including porosity by mercury intrusion porosimetry, dissolution, molecular weight by inherent viscosity (IV).

The analytical characterization demonstrated equivalent chemical composition, physical properties and performance characteristics for the subject MagnetOs Putty and the predicate devices.

The performance of the subject MagnetOs Putty was compared to that of the predicate devices in a posterolateral spine fusion animal model. The results of the study demonstrated that the performance of the subject device was equivalent to that of the predicate.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Test results included in Sections 15, 18 and 19 of this submission demonstrate that MagnetOs Putty generated equivalent results in the comparative bench, biocompatibility and pre-clinical animal testing performed compared to the predicate devices.

Overall, MagnetOs Putty has the following similarities to the predicate devices:

- has the same intended use,
- has the same product classification and product code (MQV),
- has similar Indications for Use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and is manufactured at the same facility using very similar processes as predicate, MagnetOs Granules (K161859).

CONCLUSION

The above testing demonstrates that MagnetOs Putty is as safe, as effective and performs as well as or better than the legally marketed predicate devices MagnetOs Granules (K161859, Xpand Biotechnology B.V.), AttraX Putty (K151584, Progentix B.V.), Signafuse Bioactive Bone Graft Putty (K132071, Biostructures LLC) and chronOs Composite (K071046, Synthes).