DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 24, 2017

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

Re: K161859
Trade/Device Name: MagnetOs
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: January 19, 2017
Received: January 23, 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" (21CFR 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 yours,

Mark N. Melkerson -S

Mark N. Melkerson
Division Director
Division of Orthopaedic 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)*
K161859

Device Name
MagnetOs

Indications for Use *(Describe)*
MagnetOs is an implant intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. MagnetOs 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 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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510(k) Summary MagnetOs

Date: 19 January 2017

ADMINISTRATIVE INFORMATION

Submitter details:

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	MagnetOs
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

INTENDED USE

MagnetOs is an implant intended to fill bony voids or gaps of the skeletal system, i.e., posterolateral spine. MagnetOs 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 resorbs and is replaced with bone during the healing process.

DEVICE DESCRIPTION

MagnetOs is a synthetic, osteoconductive and resorbable 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, $Ca_5(PO_4)_3OH$).

MagnetOs is gamma sterilized, comes in various sizes in granular or chip form and is sterile packaged for single use only.

EQUIVALENCE TO MARKETED DEVICE

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

- Progentix Orthobiology B.V., CuriOs™, cleared under K090641;
- Biomatlante SA, MBCP, cleared under K032268, and
- IsoTis N.V., OsSatura™ BCP, cleared under K030131.

The subject device and predicate devices K090641, K032268 and K030131 have the same intended use, the same product classification and product code (MQV), and have similar Indications for Use.

MagnetOs granules are substantially equivalent to the predicate devices CuriOs™ (K090641), MBCP (K0302268) and OsSatura™ BCP (K030131) with respect to design, structure, materials, mechanism of action, and similar Indications for Use in the posterolateral spine.

Between MagnetOs and the CuriOs™, MBCP and OsSatura™ BCP predicate devices, the limited difference are the total porosity, ratio of beta-tricalcium phosphate and hydroxyapatite.

These aspects do not affect the safety and biocompatibility of MagnetOs because of the identical nature of the building blocks of these materials and the site of application (bone).

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, biocompatibility, and performance characteristics. 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 and ISO10993-11.

Material characterization performed included the following:

- chemical composition and crystallinity was analyzed by x-ray diffraction (XRD), and Fourier transform infrared spectroscopy (FTIR),
- trace elemental analysis was performed by inductively coupled plasma/mass spectroscopy (ICP/MS),
- surface microstructure was evaluated by scanning electron microscopy (SEM), and
- physical properties including porosity by mercury intrusion porosimetry, and dissolution.

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

The performance of the subject MagnetOs 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 generated equivalent results in the comparative bench, biocompatibility and pre-clinical animal testing performed compared to the predicate devices.

Overall, MagnetOs 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, CuriOs™ Granules (K090641).

CONCLUSION

The above testing demonstrates that MagnetOs is as safe, as effective and performs as well as or better than the legally marketed predicate devices CuriOs™ (Progentix Orthobiology B.V.), OsSatura™ BCP (IsoTis N.V.) or MBCP (Biomatlante SA).