Dear Ms. 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 regulations.
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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Laurence D. Coyne -S

For Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use

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., the extremities, pelvis and posterolateral spine. In the posterolateral spine, MagnetOs Putty must be used with autograft as bone graft extender. In extremities and pelvis, MagnetOs Putty is used alone. 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.

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PRAStaff@fda.hhs.gov

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510(k) Summary

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

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Establishment registration Number
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Angela Paterson

Telephone +44 (0)7884 274 220

Date prepared:
24th October 2018
Device Classification Information:

<table>
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<th>Regulation Number</th>
<th>Device Name</th>
<th>Device Class</th>
<th>Product Code</th>
<th>Classification Panel</th>
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<td>888.3045</td>
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<td>II</td>
<td>MQV</td>
<td>Orthopedic &amp; Rehabilitation</td>
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Device Trade Name:

MagnetOs Putty

Device Common Name:

MagnetOs Putty

Intended Use:

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

Summary of substantial equivalence:

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

<table>
<thead>
<tr>
<th>Property</th>
<th>510k subject Device</th>
<th>Primary Equivalent Device</th>
<th>Equivalent Device</th>
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<tr>
<td>Device Name</td>
<td>MagnetOs Putty</td>
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</table>
The subject device MagnetOs and predicate devices Actifuse and Actifuse ABX K082575 have the same intended use, the same product classification and product code (MQV).

MagnetOs Putty is substantially equivalent to the predicate devices Actifuse and Actifuse ABX (K082575) with respect to design, structure, materials, mechanism of action, and similar Indications for Use in extremities and pelvis. Actifuse is the primary predicate device used for comparison animal studies.

Between MagnetOs Putty, Actifuse and Actifuse ABX predicate devices, the limited differences are the total porosity, ratio of beta-tricalcium phosphate: Hydroxyapatite, silicate content and the binder formulation. The LEOL binder of MagnetOs Putty has the same temporary function as the binder’s predicate device Actifuse ABX (K082575). These aspects do not affect the safety and biocompatibility of MagnetOs Putty because of the identical nature of the building blocks of these materials and the site of application (bone).

Device Description

MagnetOs Putty is a synthetic, resorbable and osteoconductive bone void filler for the repair of bony defects, containing 65-75% beta-Tri-Calcium Phosphate (TCP, Ca₃(PO₄)₂) and 25-35% Hydroxyapatite (HA, Ca₅(PO₄)₃OH) granules, premixed with a synthetic polymeric binder that provides cohesion between the granules.

MagnetOs Putty is gamma-sterilized, comes in several sizes in block form and is 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.
Performance Data

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

Biocompatibility Testing

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>.

Bench Testing (non-clinical tests)

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.

Animal Studies

The performance of MagnetOs Putty was compared to that of the predicate devices in a posterolateral spine fusion animal model and as a stand alone bone void filler for repair of defects in a critical sized femoral 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.
Safety and effectiveness

MagnetOs Putty utilizes similar technology currently found in legally marketed predicate devices. Based on testing and comparison with the predicate devices, the MagnetOs Putty indicated no adverse indications or results. It is our determination that the MagnetOs Putty is as safe and effective as the predicate devices and performs within its design specifications and is substantially equivalent to the predicate devices.