March 1, 2023

Fellowship of Orthopaedic Researchers, Inc.
% Dr. Karen Warden
President
BackRoads Consulting Inc.
PO Box 566
Chesterland, Ohio 44026

Re: K221053
Trade/Device Name: Magnes-C Anterior Cervical Plate System
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: January 24, 2023
Received: January 26, 2023

Dear Dr. Karen Warden:

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,

Colin O'neill -S

Colin O'Neill, M.B.E.
Assistant Director
DHT6B: Division of Spinal 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)*

K221053

Device Name

Magnes-C™ Anterior Cervical Plate System

Indications for Use *(Describe)*

The Magnes-C™ Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2 to T1). The system is to be used as an adjunct to fusion for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumors, pseudarthrosis or failed previous fusion.

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.***

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# 510(k) Summary

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| **Date:** | 28 February 2023 |
| **Sponsor:** | Fellowship of Orthopaedic Researchers, Inc.<br>320 Metairie Hammond Highway, Suite 406<br>Metairie, LA 70005<br>504-309-9845 |
| **Sponsor Contact:** | Stephen D. Cook, PhD, Executive Director |
| **510(k) Contact:** | Karen E. Warden, PhD<br>BackRoads Consulting<br>PO Box 566<br>Chesterland, OH 44026<br>Office: 440.729.8457 |
| **Trade Name:** | Magnes-C™ Anterior Cervical Plate System |
| **Common Name:** | Anterior cervical plate system |
| **Regulatory Class:** | Class II |
| **Classification Name, Regulation, Product Code:** | Appliance, fixation, spinal intervertebral body, 888.3060, KWQ |
| **Device Description:** | The Magnes-C™ Anterior Cervical Plate System components are intended for anterior screw fixation and stabilization of the cervical spine during the development of cervical interbody spinal fusion. The Magnes-C™ Anterior Cervical Plate System consists of one through three-level plates and fixed and variable screws, in a variety of sizes to accommodate individual patient anatomy. The Magnes-C components are provided nonsterile. Instruments to facilitate unilateral anterior fixation are included. |
| **Indications for Use:** | The Magnes-C™ Anterior Cervical Plate System is intended for anterior screw fixation of the cervical spine (C2 to T1). The system is to be used as an adjunct to fusion for the treatment of the following indications: degenerative disc disease (defined as neck pain of discogenic origin with the degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fractures or dislocations), spinal stenosis, deformity (i.e., kyphosis, lordosis or scoliosis), tumors, pseudarthrosis or failed previous fusion. |
| **Materials:** | The patient contacting portion of the Magnes-C™ Anterior Cervical Plate System implants are manufactured from titanium alloy as described by ASTM F136. All instruments are manufactured from medical grade stainless steels according to ASTM F899, some of which have silicone or Radel handles. |
| **Primary Predicate:** | Zavation Cervical Plate System (Zavation LLC – K130030) |
| **Additional Predicates:** | Cervical Spine Locking Plate (CSLP) (Synthes Spine – K945700), Biomet MaxAn® Anterior Cervical Plate System (Biomet Spine LLC – K133518) |
| **Performance Data:** | Mechanical testing of the worst case Magnes-C™ Anterior Cervical Plate System construct was performed according to ASTM F1717 and included static and dynamic compression and static torsion.<br>The mechanical test results demonstrate that the Magnes-C™ Anterior Cervical Plate System device performance is substantially equivalent to the predicate devices.<br>Additionally, MR Compatibility testing per ASTM F2503 was performed. The results demonstrate that the Magnes-C™ Anterior Cervical Plate System |

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| | can be safely scanned in an MR system. |
| **Technological Characteristics:** | The Magnes-C™ Anterior Cervical Plate System possesses the many of the same technological characteristics as the predicate devices. These include basic design, material, method of stabilization and anatomic location.<br>Differences between the subject and predicate devices did not raise new questions of safety and effectiveness. Therefore the fundamental scientific technology of the Magnes-C™ Anterior Cervical Plate System devices is similar to previously cleared devices. |
| **Conclusion:** | The Magnes-C™ Anterior Cervical Plate System possesses the same intended use and similar technological characteristics as the predicate devices. Therefore the Magnes-C™ Anterior Cervical Plate System is substantially equivalent for its intended use. |