March 4, 2020

Medacta International SA
% Mr. Chris Lussier
Director, Quality and Regulatory
Medacta USA
3973 Delp Street
Memphis, Tennessee 38118

Re: K192906
Trade/Device Name: Mecta-C Stand Alone
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: February 3, 2020
Received: February 4, 2020

Dear Mr. Lussier:

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,

for
Brent Showalter, Ph.D.
Assistant Director (Acting)
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K192906

Device Name
Mecta-C Stand Alone

Indications for Use *(Describe)*

The Mecta-C Stand Alone is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Mecta-C Stand Alone should be packed with autogenous bone graft and implanted via an anterior approach.

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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K192906 - 510(k) Summary

I. Submitter

Medacta International SA
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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Director of Quality and Regulatory, Medacta USA
Date Prepared: October 16, 2019
Date Revised: February 27, 2020

II. Device

Device Proprietary Name:	Mecta-C Stand Alone
Common or Usual Name:	Intervertebral Body Fusion Device
Classification Name:	Intervertebral Body Fusion Device
Primary Product Code:	OVE
Regulation Number:	21 CFR 888.3080
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following devices:

Primary predicate device:

- Synthes Zero-P, K112459, Synthes Spine

Additional predicate devices:

- MectaLIF Anterior, K124034, Medacta International SA
- MectaLIF Anterior Stand-Alone, K160605, Medacta International SA
- STALIF C, K120819, Centinel Spine
- STALIF C, K072415, Centinel Spine
- Anchor C, K102606, Stryker Spine
- Mosaic-C, K133218, Spinal Elements
- Mosaic-C, K071833, Spinal Elements

IV. Device Description

The Mecta-C Stand Alone implants are a line extension to Medacta's anterior cervical discectomy and fusion devices' portfolio. The Mecta-C Stand Alone implants are composed of Mecta-C Stand Alone PEEK and Mecta-C Stand Alone TiPEEK implants. The Mecta-C Stand Alone implants are intended to be used during cervical interbody fusion surgeries. The implants are characterized by different sizes of the PEEK body, in combination with different plate designs and screws. The PEEK body is available uncoated as well as with a Titanium coating.

The Mecta-C Stand Alone implants are composed of cages, plates, locking screws, lag screws, and antibackout screws.

The cages are available in various widths, heights, and lengths, with a fixed 7° of lordosis. The cages are to be inserted between two (2) cervical vertebral bodies to provide support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows the cages to be packed with bone graft.

The plates are designed with different shapes to promote a specific approach or to simplify the procedure in a specific area. The plates are assembled in front of the cage and allow for mounting of a certain number of screws. The screws are placed through the plate and cage in order to fix the device to the vertebral bodies.

The Mecta-C Stand Alone implants are designed for long-term implantation inside the human body. The implants are provided sterile in single-use packages.

V. Indications for Use

The Mecta-C Stand Alone is a stand-alone anterior cervical interbody fusion device indicated for use in skeletally mature patients with degenerative disc disease (DDD) with accompanying radicular symptoms at one level from C2-T1. DDD is defined as discogenic pain with degeneration of the disc confirmed by history and radiographic studies. These patients should have had six weeks of non-operative treatment. The interior of the spacer component of the Mecta-C Stand Alone should be packed with autogenous bone graft and implanted via an anterior approach.

VI. Comparison of Technological Characteristics

The Mecta-C Stand Alone implants and the predicate devices share the following characteristics:

- cage height;
- screw diameter;
- screw length;
- plate height;
- materials of construction;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging

The Mecta-C Stand Alone implants and the predicate devices are technologically different with respect to:

- cage width;
- cage depth;
- cage lordosis; and
- plate screw holes.

Discussion

Medacta International SA has not made any changes to the intended use, cage height, screw diameter, screw length, plate height, materials of construction, biocompatibility, device usage, sterility, shelf life, and packaging of the subject devices. Based on the comparison of technological characteristics and performance data provided within this submission, the Mecta-C Stand Alone implants are substantially equivalent to the identified predicate devices.

VII. Performance Data

Testing was conducted according to written protocols with acceptance criteria that were based on standards. The following mechanical studies were performed on worst-case implants in support of a substantial equivalence determination:

Non-Clinical Studies:

- Performance Tests
  - static compression per ASTM F2077-18;
  - static compression-shear per ASTM F2077-18;
  - static torsion per ASTM F2077-18;
  - subsidence per ASTM F2267-2004 (Reapproved 2018);
  - expulsion;
  - dynamic compression per ASTM F2077-18;
  - dynamic compression-shear per ASTM F2077-18;
  - dynamic torsion per ASTM F2077-18;
  - plate removal per ASTM F2077-18;
  - pull-out per ASTM F543-17;
  - insertion and removal torque per ASTM F543-17;
  - torsion;
  - wear testing;
  - MRI evaluation; and
  - implant imaging properties.
- Pyrogenicity
  - Bacterial Endotoxin Test (LAL test) was conducted according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and pyrogen test according to USP chapter <151> for pyrogenicity determination
  - the subject devices are not labeled as non-pyrogenic or pyrogen free

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the Mecta-C Stand Alone implants are substantially equivalent to the identified predicate devices.

Substantial equivalence has been demonstrated through a comparison of intended use, design and technological characteristics, as well as performance evaluations. The Mecta-C Stand Alone implants are as safe and effective as the identified predicate devices.