November 6, 2020

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

Re: K203076
Trade/Device Name: Mecta-C Stand Alone Extension
Regulation Number: 21 CFR 888.3080
Regulation Name: Intervertebral Body Fusion Device
Regulatory Class: Class II
Product Code: OVE
Dated: October 9, 2020
Received: October 13, 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,

Brent Showalter, Ph.D.
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K203076

Device Name
Mecta-C Stand Alone Extension

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 for one level or two contiguous levels 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 autograft bone and/or allogenic bone graft composed of cancellous, cortical and/or corticocancellous 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.

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

I. Submitter

Medacta International SA
Strada Regina
6874 Castel San Pietro (CH)
Switzerland
Phone (+41) 91 696 60 60
Fax (+41) 91 696 60 66

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 9, 2020
Date Revised: October 29, 2020

II. Device

Device Proprietary Name:	Mecta-C Stand Alone Extension
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

Primary predicate:

- Medacta International SA, Mecta-C Stand Alone, K192906

Additional predicate:

- Globus Medical Inc., Coalition MIS with Screws Coalition AGX, K173115

IV. Device Description

The Mecta-C Stand Alone implants are the same of the predicate device, Mecta-C Stand Alone cleared within K192906.
They are provided sterile in single-use packages, designed for long-term implantation inside the human body and intended to be used during cervical interbody fusion surgeries.
The Mecta-C Stand Alone implants are composed of cages, plates, locking screws, lag screws and antibackout screws.

The cages are to be inserted between two (2) cervical vertebral bodies to provide support and correction during cervical interbody fusion surgeries. They are made in PEEK uncoated or Titanium coated and they are available in various widths, heights, and lengths, with a fixed 7° of lordosis. The hollow geometry of the implants allows the cages to be packed with bone graft.
The plates, designed with different shapes to promote a specific approach or to simplify the procedure in a specific area, 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.

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 for one level or two contiguous levels 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 autograft bone and/or allogenic bone graft composed of cancellous, cortical and/or corticocancellous bone graft and implanted via an anterior approach.

VI. Comparison of Technological Characteristics

The subject Mecta-C Stand Alone is the same device of the predicate, Mecta-C Stand Alone cleared within K192906 with regards to the technological characteristics since they include exactly the same devices and the only difference is the indication for use.

The subject Mecta-C Stand Alone and the predicate devices (Coalition MIS with Screws Coalition AGX, K173115) share the following characteristics:

- indication for use;
- plate heights;
- materials;
- biocompatibility;
- device usage;
- sterility;
- shelf life; and
- packaging.

The subject Mecta-C Stand Alone differs from the predicate device (Coalition MIS with Screws Coalition AGX, K173115) with respect to:

- cage sizes;
- screw diameter;
- screw length;
- plate screw holes
- screw antibackout system; and

- bone graft volume.

VII. Performance Data

The predicate Mecta-C Stand Alone (K192906) was tested using the worst case device for each one of the following tests:

- static compression per ASTM F2077-18;
- static compression-shear per ASTM F2077-18;
- static torsion per ASTM F2077-18;
- static compression-shear without pockets
- subsidence per ASTM F2267-2018;
- expulsion;
- dynamic compression per ASTM F2077-18;
- dynamic compression-shear per ASTM F2077-18;
- dynamic torsion per ASTM F2077-18;
- dynamic compression-shear without pockets;
- plate removal;
- pull-out per ASTM F543-17;
- insertion and removal torque per ASTM F543-17;
- torsion per ASTM F543-17;
- wear testing per ISO 17853:2011;
- implant imaging properties; and
- pyrogenicity test according to USP chapters <85> and <151>

The subject devices are the same of the predicate devices (K192906); therefore no additional testing are required.

No clinical studies were conducted for the predicate (K192906) nor for the subject devices.

VIII. Conclusion

The subject device is the same of the predicate Mecta-C Stand Alone, K192906 with regards to technological characteristics. The only difference is the indication for use that is shared with the predicate Coalition MIS with Screws Coalition AGX, K173115.
Based on the comparison of technological characteristics, provided within this submission, and the performance data of the predicate devices, submitted and cleared within K192906, identical to the subject devices, the data supports the substantial equivalence of the subject Mecta-C Stand Alone with the predicate devices and thus the indication for use change object of this submission.