Medacta International SA  
℅ Elizabeth Rose, MST, RAC (US)  
Manager, Medical Devices  
Mapi USA, Inc.  
2343 Alexandria Drive, Suite 100  
Lexington, Kentucky 40504

Re: K172587  
Trade/Device Name: Mecta-C with titanium markers and Mecta-C TiPEEK with titanium markers  
Regulation Number: 21 CFR 888.3080  
Regulation Name: Intervertebral Body Fusion Device  
Regulatory Class: Class II  
Product Code: ODP  
Dated: August 25, 2017  
Received: August 28, 2017

Dear Ms. Rose:

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 (DICE) 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" (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 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 (DICE) 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,

Vincent J. Devlin -S

for

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

Enclosure
510(k) Number (if known)
K172587

Device Name
Mecta-C with titanium markers and Mecta-C TiPEEK with titanium markers

Indications for Use
The Mecta-C intervertebral body fusion device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation.

The Mecta-C device is intended for use at one level in the cervical spine, from C2-T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment prior to treatment with the device.

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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)

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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PRASStaff@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.”
3.0 510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory Affairs Manager, Medacta International SA
Date Prepared: August 25, 2017

II. Device

<table>
<thead>
<tr>
<th>Device Proprietary Name:</th>
<th>Mecta-C with titanium markers and Mecta-C TiPEEK with titanium markers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common or Usual Name:</td>
<td>Intervertebral Body Fusion Device, Cervical</td>
</tr>
<tr>
<td>Classification Name:</td>
<td>Intervertebral Body Fusion Device, Cervical</td>
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<tr>
<td>Primary Product Code:</td>
<td>ODP</td>
</tr>
<tr>
<td>Regulation Number:</td>
<td>21 CFR 888.3080</td>
</tr>
<tr>
<td>Device Classification</td>
<td>2</td>
</tr>
</tbody>
</table>

III. Predicate Device

Substantial equivalence is claimed to the following devices:
- Mecta-C, K112862, Medacta International SA
- Mecta-C TiPEEK, K142744, Medacta International SA

IV. Device Description

The purpose of this submission is to add the Mecta-C with titanium markers and the Mecta-C TiPEEK with titanium markers to Medacta’s Mecta-C product offering. The Mecta-C with titanium markers and the Mecta-C TiPEEK with titanium markers are intervertebral body fusion devices intended for stabilization and to promote bone fusion during the normal healing process following surgical correction of disorders of the cervical spine. The Mecta-C and the Mecta-C TiPEEK intervertebral body fusion devices are indicated for the treatment of degenerative diseases of the cervical disc and can be used for cervical fusion from C2-T1.

The Mecta-C with titanium markers are intervertebral body fusion devices manufactured with an implant grade polyetheretherketone (PEEK) body and titanium markers. The Mecta-C
TiPEEK with titanium markers are intervertebral body fusion devices manufactured with a PEEK body, commercially pure titanium (CPTi) coating, and titanium markers. The markers’ material is changing from tantalum to titanium to reduce artefact during imaging scans.

The titanium marker’s spikes are also being modified to reduce the conical edge from 90° to 50°. The purpose of the conical edge change is to create a sharper tip design which allows for better penetration of the titanium pin and a more uniform contact between the PEEK cage and vertebral body.

The markers are placed in the implant on each end of the TiPEEK cages to allow easier radiological assessment of the position and orientation of the radiolucent TiPEEK cages.

The cages are offered in various widths, heights, footprint geometries, and lordosis which can be inserted between two cervical vertebra bodies to give support and correction during cervical interbody fusion surgeries. The hollow geometry of the implants allows them to be packed with autogenous bone graft.

V. Indications for Use

The Mecta-C intervertebral body fusion device is indicated for anterior cervical interbody fusion procedures in skeletally mature patients. The device systems are designed for use with autogenous bone graft to facilitate fusion. One device may be used per intervertebral space. The implants are intended to be used with supplemental spinal fixation.

The Mecta-C device is intended for use at one level in the cervical spine, from C2-T1, for the treatment of cervical disc disease (defined as neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies). The cervical device is to be used in patients who have had six weeks of non-operative treatment prior to treatment with the device.

VI. Comparison of Technological Characteristics

The Mecta-C with titanium markers, the Mecta-C TiPEEK with titanium markers, and the predicate devices share the following characteristics:

- cage and coating materials of construction;
- cage design;
- sterility;
- diameter;
- shelf life; and
- packaging.
The Mecta-C with titanium markers and the Mecta-C TiPEEK with titanium markers are technologically different from the predicate devices as the markers’ material of construction has changed and the conical edge has been reduced to 50°.


These materials have a long history of use in implantable orthopedic devices and material information has been provided in previous Medacta 510(k) submissions for the Mecta-C (K112862) and Mecta-C TiPEEK (K142744).

Due to the extensive history of use in currently marketed medical devices, as well as identical manufacturing processes between the subject and predicate devices the Mecta-C (K112862) and the Mecta-C TiPEEK (K142744), additional biocompatibility testing was deemed unnecessary for the Mecta-C with titanium markers and the Mecta-C TiPEEK with titanium markers.

A comparison of the subject and predicate devices is provided in the table below.

<table>
<thead>
<tr>
<th>Parameters</th>
<th>Mecta-C with titanium markers and Mecta-C TiPEEK with titanium markers</th>
<th>Mecta-C PEEK and Mecta-C TiPEEK (K112862 and K142744)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Height</td>
<td>4 mm - 9 mm</td>
<td>4 mm - 9 mm</td>
</tr>
<tr>
<td>Lordosis</td>
<td>5° and 7°</td>
<td>5° and 7°</td>
</tr>
<tr>
<td>Width</td>
<td>14 mm, 16 mm, and 18 mm</td>
<td>14 mm, 16 mm, and 18 mm</td>
</tr>
<tr>
<td>Depth</td>
<td>12 mm, 14 mm, and 15 mm</td>
<td>12 mm, 14 mm, and 15 mm</td>
</tr>
<tr>
<td>Material of Construction</td>
<td>Cage: PEEK and PEEK w/CPTi coating Markers: titanium</td>
<td>Cage: PEEK and PEEK w/CPTi coating Markers: tantalum</td>
</tr>
<tr>
<td>Conical Edge</td>
<td>50°</td>
<td>90°</td>
</tr>
<tr>
<td>Device Usage</td>
<td>Single Use</td>
<td>Single Use</td>
</tr>
</tbody>
</table>
### Discussion

The technological differences between the subject and predicate devices do not raise new questions of safety and effectiveness. As seen above, the Mecta-C with titanium markers and the Mecta-C TiPEEK with titanium markers are identical to the predicate devices in terms of materials of construction (except markers material), design, diameter, sterility, and packaging. Performance data provided within this submission supports that the Mecta-C with titanium markers and the Mecta-C TiPEEK with titanium markers are substantially equivalent to the identified predicate devices.

### VII. Performance Data

As the subject devices are a line extension to previously cleared devices, verification activities, as identified through risk analysis, were previously conducted on the worst-case implants to written protocols with pre-defined acceptance criteria. Engineering rationales determined that the proposed implants did not represent a new worst-case for mechanical testing.

The following performance tests were conducted on the predicate devices and reviewed as part of the Mecta-C (K112862) and the Mecta-C TiPEEK (K142744) submissions:

- shear testing;
- tension testing;
- shear and bonding fatigue;
- coating characterization;
- abrasion resistance;
- mechanical testing;
- subsidence testing;
- wear testing; and
- implant imaging properties – artefacts reduction.

### Pyrogenicity

- Medacta uses both the Bacterial Endotoxin Test (LAL test) according to European Pharmacopoeia §2.6.14 (which is equivalent to USP chapter <85>) and the Pyrogen Test according to USP chapter <151> for pyrogenicity determination.
• Medacta does not intend to label the subject devices as non-pyrogenic or pyrogen free.

VIII. Conclusion

Based on the above information, the Mecta-C with titanium markers and the Mecta-C TiPEEK with titanium markers can be considered 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 with titanium markers and the Mecta-C TiPEEK with titanium markers are as safe and effective as the predicate devices, Mecta-C (K112862) and Mecta-C TiPEEK (K142744).