December 7, 2023

Medacta International SA
% Mr. Christopher Lussier
Senior Director, Quality, Regulatory and Clinical Research
Medacta USA
6386 Global Drive, Suite 101
Memphis, Tennessee 38141

Re: K231515
Trade/Device Name: MySpine Cervical Guides
Regulation Number: 21 CFR 888.3075
Regulation Name: Posterior Cervical Screw System
Regulatory Class: Class II
Product Code: QSD
Dated: May 25, 2023
Received: November 27, 2023

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 (the 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 available 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.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

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 Part 803) for devices or postmarketing safety reporting (21 CFR Part 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 Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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.

Submission Number *(if known)*

K231515

Device Name

MySpine Cervical Guides

Indications for Use *(Describe)*

MySpine Cervical is intended to be used with any 510(k) cleared, legally marketed, posterior cervical screw system (for its cleared indications for use) and its respective compatible components for cervical posterior spinal fixation procedures intended for fusion. MySpine Cervical guides are patient specific devices intended to be used as anatomical perforating guides, specific to a single patient's anatomy, to assist intra-operatively in the positioning of screws during posterior cervical fixation surgery between the levels of C2 to C7.
For pedicle diameters equal or less than ø4mm, Medacta provides the guides for the pilot hole preparation into the lateral mass without penetrating the pedicle.
The use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical placement of the implants based upon the radiological images of the patients' anatomical landmarks and the selected surgical equipment. These components include patient-specific guides fabricated based on the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. MySpine Cervical guides are intended for single use only.

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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510(k) Summary

I. Submitter

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Contact Person: Stefano Baj, Regulatory and Compliance Director, Medacta International SA
Applicant Correspondent: Chris Lussier, Senior Director, Quality, Regulatory, and Clinical Research, Medacta USA
Date Prepared: May 25, 2023

II. Device

Device Proprietary Name:	MySpine Cervical Guides
Common or Usual Name:	Posterior cervical screw placement guide
Classification Name:	Posterior Cervical Screw System
Primary Product Code	QSD
Regulation Number:	21 CFR 888.3075
Device Classification	II

III. Predicate Device

Substantial equivalence is claimed to the following primary predicate device:

- FIREFLY Cervical Navigation Guide, K220132, Mighty Oak Medical Inc.

Additionally, the following predicate devices are used within the submission:

- MySpine Pedicle Screw Placement Guides Extension, K203673, Medacta International SA
- MySpine Pedicle Screw Placement Guides – MC and Drill Pilot Instruments, K173472, Medacta Interational SA

IV. Device Description

MySpine Cervical guides are patient specific devices intended to be used as anatomical perforating guides, specific to a single patient's anatomy, to assist intra-operatively in the positioning of screws during posterior cervical fixation surgery between the levels of C2 to C7.

The MySpine software platform allows the surgeon to complete 3D pre-operative planning based on the patient's spinal CT scans. CT images are used to create a 3D model of the vertebrae that will represent

the template used to generate the corresponding MySpine Cervical Guide fitting the patient's vertebral anatomy.
The MySpine Cervical Guides as well as their bone models are single-use and they can be provided in sterile or non-sterile version.

V. Indications for Use

MySpine Cervical is intended to be used with any 510(k) cleared, legally marketed, posterior cervical screw system (for its cleared indications for use) and its respective compatible components for cervical posterior spinal fixation procedures intended for fusion. MySpine Cervical guides are patient specific devices intended to be used as anatomical perforating guides, specific to a single patient's anatomy, to assist intra-operatively in the positioning of screws during posterior cervical fixation surgery between the levels of C2 to C7. For pedicle diameters equal or less than ø4mm, Medacta provides the guides for the pilot hole preparation into the lateral mass without penetrating the pedicle.
The use of the guides involves a surgical planning software, with which the surgeon preoperatively plans the surgical placement of the implants based upon the radiological images of the patients' anatomical landmarks and the selected surgical equipment. These components include patient-specific guides fabricated based on the surgical plan to precisely reference the placement of the implant components intra-operatively per the surgical plan. MySpine Cervical guides are intended for single use only.

VI. Comparison of Technological Characteristics

The subject MySpine Cervical Guides are substantially equivalent to the predicate device, FIREFLY Cervical Navigation Guide (K220132), with regards to the following characteristics:

- Lateral mass guides' design;
- Instruments compatibility;
- Manufacturing process;
- Material;
- Biocompatibility;
- Device usage; and
- Packaging.

The subject MySpine Cervical Guides differ respect to the predicate, FIREFLY Cervical Navigation Guide (K220132), with regards to the following characteristics:

- Body region;
- Unilateral guides' design;
- Spinous process contact;
- Design workflow & related software;
- Sterility; and
- Shelf-life.

Discussion
The technological differences between the subject and primary predicate device do not raise new questions of safety and effectiveness since the main differences (i.e. spinous process contact, design workflow & related software, sterility and shelf-life) of the subject devices are shared with Medacta MySpine devices cleared within K203673 and K173472.

Medacta International SA has not made any change to the manufacturing process, material, device usage, biocompatibility, sterility, shelf life, and packaging of the subject devices with respect to the predicate devices.
The comparison of technological characteristics and performance data provided within the submission supports the substantial equivalence of the subject devices respect to the predicate devices.

VII. Performance Data

Based on the risk analysis, testing activities were conducted to written protocols. The following validations and rationale are provided in support of the substantial equivalence determination:

Non-Clinical Studies

- Design Validation workshops to validate the design and the overall functionality of the subject device as well as to evaluate their accuracy. Two validation workshops, one for the unilateral and the other for the mass lateral guides, have been performed.
- MySpine Cervical stability assessment to evaluate the stability of the subject lateral mass guides.
- Biocompatibility data, shelf-life and sterilization validation studies submitted in support of the predicate devices were leveraged.

Clinical Studies:

- No clinical studies were conducted.

VIII. Conclusion

The information provided above supports that the subject devices are substantially equivalent to the predicate devices.