



OrthoGrid Systems Inc.
% Sebastian Edin
Regulatory Affairs Consultant
3216 South Highland, Suite 202
SALT LAKE CITY UT 84106

December 7, 2019

Re: K192279

Trade/Device Name: PhantomMSK Trauma
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: November 4, 2019
Received: November 13, 2019

Dear Sebastian Edin:

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

Thalia T. Mills, Ph.D.
Director
Division of Radiological Health
OHT7: Office of In Vitro Diagnostics
and Radiological Health
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K192279

Device Name

PhantomMSK Trauma

Indications for Use (Describe)

PhantomMSK Trauma is an image-processing software indicated to assist in the positioning of Orthopedic Trauma components. It is intended to assist in precisely positioning Orthopedic Trauma components intraoperatively by measuring their positions relative to the bone structures of interest, provided that the points of interest can be identified from radiology images. Clinical judgement and experience are required to properly use the device. The device is not for primary image interpretation. The software is not for use on mobile phones.

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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510(k) SUMMARY

K192279

OrthoGrid Systems, Inc.'s PhantomMSK Trauma

Date Prepared: 08/19/2019

Submitter: OrthoGrid Systems Inc.
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Contact Person: Sebastian Edin
Regulatory Affairs Consultant
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Name of Device: PhantomMSK Trauma

Classification Name: Picture Archiving and Communications System (21 CFR 892.2050)

Regulatory Class: Class II

Product Code: LLZ

Predicate Devices: PhantomMSK (K182332)

Device Description:

The PhantomMSK Trauma is a non-invasive software system that provides image analysis tools for Orthopedic Trauma procedures that use fluoroscopic imaging to assist with implant, instrument and anatomic alignment. PhantomMSK Trauma provides templating, measurement, and distortion correction tools for intraoperative fluoroscopic image assessment. PhantomMSK Trauma does not include any custom computer hardware and is a software-based device that can be run on a "commercial off-the-shelf" system (i.e. PC, keyboard, mouse, touchscreen monitor etc.) that meet minimum performance requirements. Furthermore, PhantomMSK Trauma operates on image principles that are not vendor specific. To operate PhantomMSK Trauma, a fluoroscopic image is acquired from a C-arm and displayed outside the sterile field, where the image analysis tools can be used at the surgeon's discretion.

Fluoroscopic distortion is attributed to external electromagnetic interference and the mapping of the planar image on a curved input phosphor. The PhantomMSK Trauma uses software features in conjunction with its radiopaque calibration array, which attaches to the C-arm image intensifier, to calculate and correct for fluoroscopic distortion.

Intended Use / Indications for Use:

PhantomMSK Trauma is an image-processing software indicated to assist in the positioning of Orthopedic Trauma components. It is intended to assist in precisely positioning Orthopedic Trauma components intraoperatively by measuring their positions relative to the bone structures of interest, provided that the points of interest can be identified from radiology images. Clinical judgement and

experience are required to properly use the device. The device is not for primary image interpretation. The software is not for use on mobile phones.

Substantial Equivalence:

The PhantomMSK Trauma is shown to be substantially equivalent to its predicate, PhantomMSK. The PhantomMSK Trauma has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended surgical use of the device and do not raise new question of safety or effectiveness when used as labeled.

Company	OrthoGrid Systems, Inc.	OrthoGrid Systems, Inc.
Product Name	PhantomMSK Trauma	PhantomMSK
FDA 510(k) #	-	K182332
Product Code	LLZ	LLZ
Principles of Operation	The subject device is an image processing software. A fluoroscopic image is acquired from a C-arm by the software and displayed outside the sterile field, where the image analysis tools can be used at the surgeon's discretion.	The predicate device is an image processing software. A fluoroscopic image is acquired from a C-arm by the software and displayed outside the sterile field, where the image analysis tools can be used at the surgeon's discretion.
Image Data	C-arm, X-ray	C-arm, X-ray
Features	Templating, distortion correction, measurements, PACS and Network compatibility.	Templating, distortion correction, measurements.

Testing:

Verification and validation testing were done at the code and system level according to written test protocols established before testing was conducted to ensure that all templating overlay, measurement, and distortion correction tools performed as expected. Specifically, testing was performed with the GE OEC 9900 and 9800 Composite Video Signal and for C-arms having an outer diameter of the image intensifier ranging between 34.5 to 38.5 cm and 28.6 to 33 cm.

The test results were reviewed by designated technical professionals to ensure acceptability criteria were satisfied prior to the release of the software.

The results are summarized in test summary reports. The conclusion states that:

- Verification strategies and test procedures used are appropriate
- System test procedures trace to requirements
- All requirements are tested or otherwise verified
- Test results meet the required pass/fail criteria

Conclusion:

The PhantomMSK Trauma is shown to be substantially equivalent to its predicate, PhantomMSK. The PhantomMSK Trauma has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate device. The minor differences in indications do not alter the intended surgical use of the device and do not raise new question of safety or effectiveness when used as labeled. In addition, performance data demonstrate that the PhantomMSK Trauma does not raise different questions of safety or effectiveness. Thus, the PhantomMSK Trauma is substantially equivalent.