



February 27, 2020

Omnia Medical, LLC
% Mr. Daniel Johnson
Regulatory Engineer
JALEX Medical
30311 Clemens Road, Suite 5D
Westlake, Ohio 44145

Re: K192096

Trade/Device Name: Omnia Medical Trauma Screws
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: HWC
Dated: January 30, 2020
Received: January 31, 2020

Dear Mr. Johnson:

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,

Ronald P. Jean, Ph.D.
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

Indications for Use

510(k) Number (if known)

K192096

Device Name

Omnia Medical Trauma Screws

Indications for Use (Describe)

The Omnia Medical Trauma Screws are intended for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

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

Submitted By: Omnia Medical, LLC
6 Canyon Road Suite 300
Morgantown, WV 26508

Date: 2/26/2020

Contact Person: Daniel Johnson, Regulatory Engineer
Contact Telephone: (440) 541-0060
Contact Fax: (440) 933-7839

Device Trade Name: Omnia Medical Trauma Screws
Device Classification Name: Smooth or threaded metallic bone fixation fastener (21 CFR 888.3040)
Device Classification: Class II
Reviewing Panel: Orthopedic
Product Code: HWC

Predicate Devices:

Table 1: Predicate Device Table

Subject Device	Primary Predicate
Omnia Medical Trauma Screws	Depuy Synthes 4.0 Cannulated Screw (K161616)

The Depuy Synthes 4.0 cannulated screw has never been subject to a recall.

Device Description:

The Omnia Medical Trauma screws are manufactured from Ti-6Al-4V ELI per ASTM F136. The screws are available in a variety of lengths and diameters to accommodate varying patient anatomy.

Indications for Use:

The Omnia Medical Trauma Screws are intended for use in bone reconstruction, osteotomy, arthrodesis, joint fusion, fracture repair, and fracture fixation of bones appropriate for the size of the device.

Comparison of Technological Characteristics with Predicate devices:

The Omnia Medical Trauma Screws and the predicate have the same intended use and fundamental scientific technology. A comparison table of the subject device and predicate devices technological characteristics is provided in this submission in Section XV Substantial Equivalence. There are no differences in technological characteristics that raise questions of safety and efficacy.

Performance Data:

Substantial equivalence of the Omnia Medical Trauma Screws is supported by engineering rationale provided in the relevant sections of this submission.

Based on the indications for use, technological characteristics, and comparison with the predicate device, the subject device has demonstrated substantial equivalence.