September 22, 2020

AzurMeds inc.
Jean-Marie Berger
Chief Commercial Officer
4809 N Ravenswood Avenue Suite 119
Chicago, Illinois 60604

Re: K200987
Trade/Device Name: LTJ Screws and Washer
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: HWC, HTN
Dated: September 9, 2020
Received: September 11, 2020

Dear Jean-Marie Berger:

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 - Shumaya Ali, M.P.H.
Assistant Director
DHT6C: Division of Restorative, Repair
and Trauma 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.

510(k) Number *(if known)*
K200987

Device Name
LTJ Screws and Washer

Indications for Use *(Describe)*
The LTJ Screws (3.75mm solid and 4.5mm cannulated) are intended to be used in skeletally mature patient as stand-alone bone screws for bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Optional washers are available for the 3.75 solid screws.

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

AzurMeds., Inc's LTJ Screws and Washer

Date prepared: September 17th, 2020

Assigned 510(k) number:	K200987
Company:	AzurMeds Inc. 4809 N Ravenswood Ave 119 CHICAGO, IL, 60640, USA Phone: + 1 (773)-564-9324 Cell: + 1 (612) 810-7221
Contact:	Jean-Marie Berger
Trade/Proprietary Name:	LTJ Screws and Washer
Regulation & Classification Name:	(Primary) 21 CFR 888.3040 - Smooth or threaded metallic bone fixation fastener 21 CFR 888.3030 – Single/multiple component metallic bone fixation appliances and accessories
Product Code & Common Name:	HWC (Screw, Fixation, Bone) HTN (Washer, Bolt Nut)
Primary Predicate Device:	Monster Screw System™ (K124027)

1. Device Description

The LTJ Screws are partially threaded solid headless 3.75 mm screws and partially threaded cannulated headed 4.5 mm screws provided in various length ranging from 26 mm to 50 mm. They are provided in Stainless Steel Alloy compliant with ASTM F138. The headless implants can be associated to an LTJ diameter 8 mm Washer provided in Stainless Steel Alloy compliant with ASTM F138. It is essential to handle and insert implants with LTJ instruments specifically designed for this purpose.

2. Indications for use

The LTJ Screws (3.75mm solid and 4.5mm cannulated) are intended to be used in skeletally mature patient as stand-alone bone screws for bone reconstruction, osteotomy, arthrodesis, joint fusion, ligament fixation, fracture repair and fracture fixation, appropriate for the size of the device. Optional washers are available for the 3.75 solid screws.

3. Comparison of Technological Characteristics with the Predicate Device

The subject and predicate screws are both metallic screw systems that contain similar diameters and lengths. The subject system differs from the predicate system because it contains a subset of diameters and lengths, it is manufactured out of a different grade of stainless steel and contains a different thread profile.

4. Performance data

Mechanical testing of the worst-case LTJ Screws included torque strength, insertion/removal torque and pullout performed according to ASTM F543. The mechanical test results demonstrated that the LTJ Screws and Washer are adequate for their intended use.

5. Conclusion

LTJ Screws and Washer possess the same intended use, similar indications, and same principles of operation as its predicate device. While the LTJ Screws and Washer are not identical to the predicate devices, comparisons of the subject and predicate devices confirmed that any differences in technological characteristics do not raise different questions of safety and effectiveness than the predicate device. Therefore, the LTJ Screws and Washer system is substantially equivalent to currently marketed predicate device for its intended use.