October 17, 2023

Foundation Fusion Solutions, LLC (dba CornerLoc)
℅ Jeffrey Brittan
Vice President of Product Realization
Watershed Idea Foundry
1815 Aston Ave., Suite 106
Carlsbad, California 92008

Re: K232878
Trade/Device Name: TransLoc 3D
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth Or Threaded Metallic Bone Fixation Fastener
Regulatory Class: Class II
Product Code: OUR, HWC
Dated: September 14, 2023
Received: September 18, 2023

Dear Jeffrey Brittan:

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.

510(k) Number *(if known)*
K232878

Device Name
TransLoc 3D

Indications for Use *(Describe)*

The TransLoc 3D Screw is intended for sacroiliac joint fusion for conditions including:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

The TransLoc 3D Posterior Implant is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the TransLoc 3D Posterior Implant is implanted, it must be used with a TransLoc 3D Screw implanted across the same sacroiliac joint.

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

DATE PREPARED
October 16, 2023

MANUFACTURER AND 510(k) OWNER
Foundation Fusion Solutions, LLC dba CornerLoc
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REPRESENTATIVE/CONSULTANT
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PROPRIETARY NAME OF SUBJECT DEVICE
TransLoc 3D

COMMON NAME
Sacroiliac joint fixation device

DEVICE CLASSIFICATION
Smooth or threaded metallic bone fixation fastener
(Classification Regulation: 21 CFR 888.3040, Product Codes: OUR, HWC, Class: II)

PREMARKET REVIEW
Orthopedic Panel

INDICATIONS FOR USE
The TransLoc 3D Screw is intended for sacroiliac joint fusion for conditions including:

- Sacroiliac joint dysfunction that is a direct result of sacroiliac joint disruption and degenerative sacroiliitis. This includes conditions whose symptoms began during pregnancy or in the peripartum period and have persisted postpartum for more than 6 months.
- To augment immobilization and stabilization of the sacroiliac joint in skeletally mature patients undergoing sacropelvic fixation as part of a lumbar or thoracolumbar fusion.
- Acute, non-acute, and non-traumatic fractures involving the sacroiliac joint.

The TransLoc 3D Posterior Implant is intended for sacroiliac joint fusion for conditions including sacroiliac joint disruptions and degenerative sacroiliitis. When the TransLoc 3D Posterior Implant is implanted, it must be used with a TransLoc 3D Screw implanted across the same sacroiliac joint.

DEVICE DESCRIPTION
TransLoc 3D implants are intended to transfix the sacroiliac (SI) joint for fusion procedures. These titanium 3D-printed devices are available in a range of lengths and include a threaded Screw version, as well as a Posterior Implant version that incorporates circumferential teeth and a porous lattice pattern. The TransLoc 3D Screw may be implanted alone and may be used in the same procedure with CornerLoc bone graft. The TransLoc 3D Posterior Implant is intended only for use along with a TransLoc 3D Screw implanted in the same sacroiliac joint. All implants are provided sterile packaged for single use. Non-sterile instruments are available to assist with the surgical procedure and must be sterilized prior to use.

PREDICATE DEVICE IDENTIFICATION
TransLoc 3D is substantially equivalent to the following predicate:

510(k) Number	*Predicate Manufacturer & Device Name*
K211496	Foundation Fusion Solutions, LLC dba CornerLoc TransLoc 3D (*Primary Predicate*)

K223819, Alevio, LLC SI-Cure Sacroiliac Fusion System and K222512, OsteoCentric Technologies Integrity-SI Fusion System, and K021932, Synthes 6.5mm Cannulated Screw are also cited in this submission.

SUMMARY OF NON-CLINICAL TESTING
Engineering analysis demonstrated that the modifications associated with this submission do not present a new worst-case construct and do not impact the performance of the device, including with respect to mechanical testing. Additional performance testing was not required.

SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARISON
CornerLoc believes that TransLoc 3D is substantially equivalent to the predicate TransLoc 3D devices. The subject device has the same design, materials, manufacturing methods, and sterilization, and it continues to have the same intended use to bridge both sides of the SI joint to prevent motion. These technological characteristics have undergone analysis to ensure the subject device is equivalent to the predicate.

CONCLUSION
Based on the analysis performed it can be concluded that the subject device does not raise new issues of safety or efficacy compared to the predicate device. The indications for use, technological characteristics, and performance characteristics for the proposed TransLoc 3D updates are assessed to be substantially equivalent to the predicate.