July 27, 2022

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

Re: K211496
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
Dated: June 28, 2022
Received: June 29, 2022

Dear Mr. 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 (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

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)*
K211496

Device Name
TransLoc 3D

Indications for Use *(Describe)*

TransLoc 3D 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.

510(k) Summary

DATE PREPARED
July 22, 2022

MANUFACTURER AND 510(k) OWNER
Foundation Fusion Solutions, LLC dba CornerLoc
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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 Regulations: 21 CFR 888.3040, Product Code: OUR, Class: II)

PREMARKET REVIEW
Orthopedic Panel

INDICATIONS FOR USE
TransLoc 3D 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
The TransLoc 3D System 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 Posterior Implant version that incorporates circumferential teeth and a porous lattice pattern. The TransLoc 3D Screw may be implanted alone. The TransLoc 3D Posterior Implant is intended only for use along with a TransLoc 3D Screw implanted in the same sacroiliac joint.

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

510(k) Number	*Predicate Manufacturer & Device Name*
K021932	Synthes 6.5mm Cannulated Screw (*Primary Predicate*)
K180818	Tenon Medical Catamaran Sacroiliac Joint Fixation System (CAT SIJ Fixation System)
K200696	Orthofix FIREBIRD SI Fusion System

The following reference device is also cited in this submission:

- Nvision Biomedical's Trigon Ti Stand-Alone Wedge Fixation System (K192645)

SUMMARY OF NON-CLINICAL TESTING
No FDA performance standards have been established for TransLoc 3D. Testing was performed, and results demonstrated that TransLoc 3D is substantially equivalent to the predicate devices.

- Dynamic compression-shear (ASTM F2077)
- Dynamic 3-point bending (ASTM F2193)
- Static and dynamic cantilever bending (ASTM F2193)
- Insertion and pullout/pushout testing (ASTM F543)
- Cadaver implantation and biomechanical studies (lab protocols)
- Particulate analysis (USP <788>)

COMPARISON OF TECHNOLOGICAL CHARACTERISTICS
CornerLoc believes that TransLoc 3D is substantially equivalent to the identified predicate devices. The subject device has similar design, similar dimensions, and uses similar or identical materials. The subject device has the same indications for use and intended use, as well as similar technological characteristics (threaded and non-threaded titanium implant designs in a range of similar lengths with fixation features that bridge both sides of the SI joint to prevent motion). These technological characteristics have undergone testing/analysis to ensure the subject device is equivalent to the predicates.

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