March 18, 2022

Fixier, S.A. de C.V.
% Aurelia Brownridge
Regulatory Affairs Consultant
Aurelia Brownridge
11594 Cesped Drive
San Diego, California 92124

Re: K201510
Trade/Device Name: Traufix osteosynthesis, osteotomy, and arthrodesis devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HRS, HWC

Dear Aurelia Brownridge:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated February 18, 2022. Specifically, FDA is updating this SE Letter as an administrative correction, as two copies of the SE letter were sent in error along with the Indications for Use statement for K201510, but not the 510(k) Summary.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Shumaya Ali, M.P.H., OHT6: Office of Orthopedic Devices, (301) 796-2356, shumaya.ali@fda.hhs.gov.

Sincerely,

Shumaya Ali -S

Shumaya Ali, MPH
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

February 18, 2022

Fixier, S.A. de C.V.
% Aurelia Brownridge
Regulatory Affairs Consultant
Aurelia Brownridge
11594 Cesped Drive
San Diego, California 92124

Re: K201510
Trade/Device Name: Fixier osteosynthesis, osteotomy, and arthrodesis devices
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: HRS, HWC
Dated: January 15, 2022
Received: January 20, 2022

Dear Aurelia Brownridge:

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,

Shumaya Ali -S

Shumaya Ali, MPH
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)*
K201510

Device Name

Traufix osteosynthesis, osteotomy, and arthrodesis devices

Indications for Use *(Describe)*

Traufix medical devices are intended for fixation of fractures and osteotomies of various bones including the pelvis, clavicle, scapula, humerus, ulna, radius, femur, tibia, olecranon, and fibula.

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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Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary - K201510

The following 510(k) summary has been prepared pursuant to requirements specified in 21 CFR 807.92.

510(k) Bundle: This submission includes a range of Fixier's products with the same regulation classification and regulation code name.

Date Summary Prepared: February 15, 2022

Manufacturer and Contact Information:

Submitter's Name	Submitter's Physical Address	Submitter's Contact Information
Fixier, S.A. de C.V.	Carretera Doctor Mora a San Miguel de Allende km 3.4, C.P. 37967 Comunidad de San Rafael, Doctor Mora, Guanajuato, México	**Primary Official Contact:** Aurelia Brownridge Regulatory Affairs (Consultant) Telephone: 760-497-4354
		Secondary Contact: Vianey Mariana Perez Suarez Biological and Pharmaceutical Chemistry Regulatory Affairs Chief Telephone: 011-52-419-688-11-91

Device and Classification Information:

Proprietary Name:	Traufix osteosynthesis, osteotomy, and arthrodesis devices
Common Name:	Plate, Fixation, Bone (primary) Screw, Fixation, Bone
Classification Name:	Single/multiple component metallic bone fixation appliances and accessories (primary) Smooth or threaded metallic bone fixation fastener
Regulatory Class:	II
Product Codes:	HRS (primary) HWC
Regulation Number:	21 CFR 888.3030 (primary) 21 CFR 888.3040

Indications for Use: Traufix medical devices are intended for fixation of fractures and osteotomies of various bones including the pelvis, clavicle, scapula, humerus, ulna, radius, femur, tibia, olecranon, and fibula.

Description: Traufix osteosynthesis medical devices are metal implants (stainless steel per ASTM F138, or ASTM F139, or titanium-alloy per ASTM F136) fixed adjacent to the bone for the treatment and consolidation of fractures, osteotomies, and/or joint ossification. The devices include different types and sizes of plates and screws. The product's list is shown below:

Plate type	Plate code	Plate description	Screw code	Screw description	Surgical technique #	Surgical technique name
Mini fragments	017	2.7 DCP Plates	064	2.7mm cortex screw	TQ-005	DCP plates
	207	2.0 DCP Plates	079	2.0mm cortex screw		
	202 & 203	2.7mm L-plate	064	2.7mm cortex screw	TQ-032	T and L plates for 3.5mm, 2.7mm, and 2.0mm screws
Small fragments	016	3.5mm One-third tubular plate	057	3.5mm cortex screw	TQ-004	3.5mm One-third tubular plate
			058	4.0mm cancellous screw partially threaded		
			059	4.0mm cancellous screw fully threaded		
	110, 111, 172, & 173	ALP titanium distal tibia plates TIDIS & TIDIS-III	112	3.5mm titanium cortex screw	TQ-011	ALP titanium distal tibia plate TIDIS I AND TIDIS III
			106	3.5mm titanium cortex locking screw		
			107	3.5mm titanium cancellous locking screw		
	129	ALP titanium proximal humerus plate PROH-LOCK LARGE	112	3.5mm titanium cortex screw	TQ-014	ALP titanium humerus plate PROH-LOCK and PROH-LOCK LARGE
			106	3.5mm titanium cortex locking screw		
			107	3.5mm titanium cancellous locking screw		
	144 & 145	ALP titanium distal lateral humerus plate DH-LOCK	112	3.5mm titanium cortex screw	TQ-017	ALP titanium distal lateral humerus plate and ALP titanium Distal medial humerus plate DH-LOCK
			106	3.5mm titanium cortex locking screw		
			107	3.5mm titanium cancellous locking screw		
			170	2.7mm titanium cortex locking screw		
	148, 148S, 149, & 149S.	ALP titanium distal radius plate LIONTER	154X	2.5mm titanium cortex screw Torx drive	TQ-018	ALP titanium distal radius plate
			155X	2.5mm titanium cortex locking screw Torx drive		

Plate type	Plate code	Plate description	Screw code	Screw description	Surgical technique #	Surgical technique name
	164 & 165	ALP titanium distal tibia plates TIDIS-III	112	3.5mm titanium cortex screw	TQ-023	ALP titanium distal plate TIDIS II
			106	3.5mm titanium cortex locking screw		
			107	3.5mm titanium cancellous locking screw		
Large fragments	023	4.5mm Reconstruction plates	056	4.5mm cortex screw	TQ-009	Reconstruction plates
			060	6.5mm cancellous screw 16mm thread		
			061	6.5mm cancellous screw 32mm thread		
			062	6.5mm cancellous screw fully threaded		
	150 & 151	ALP titanium proximal femur plate TLP	126	4.5mm titanium cortex screw	TQ-019	ALP titanium proximal femur plate TLP
			108	5.0mm titanium cortex locking screw		
			171	5.0mm titanium cannulated cortex locking screw		
			109	5.5mm titanium cancellous locking screw		
			156	7.3mm titanium cannulated cancellous locking screw		
	152 & 153	ALP titanium proximal tibia plate OPTIMUS	126	4.5mm titanium cortex screw	TQ-020	ALP titanium proximal Tibia plate OPTIMUS
			108	5.0mm titanium cortex locking screw		
			109	5.5mm titanium cancellous locking screw		

Substantial Equivalence:

Traufix osteosynthesis, osteotomy, and arthrodesis devices and predicate devices have the same indications for use, target population, patient contact, materials, and sterilization methods.

Traufix subject devices, and predicate devices are intended for fracture fixation and minor differences exist in the physical shape and dimension characteristics of the plates and screws. However, these minor dimensional differences do not raise any new questions of safety or effectiveness.

Primary Predicate Device:

AUXEIN BRAND Of Bone Plates and Bone Screws & AUXEIN BRAND Of DCS Plate System AUXEIN brand of Locking Plates and Locking Screws, (K141680)

Other Predicate Devices:	-Synthes (USA) Modular Mini Fragment LCP System, (K063049) -Synthes (USA) Medial Distal Tibia Plates, (K001945) -Synthes Variable Angle Locking Compression Plate (VA-LCP), (K071184) -Synthes One-Third Tubular DCL Plate, (K011335) -Synthes 4.5mm LCP Straight Reconstruction Plates, (K051986) -Synthes (USA) LCP Proxima Humerus Plates, Long, (K041860)
Non-Clinical (Performance Testing):	-Non-clinical testing was performed in the subject devices as follows: -Single cycle bend testing was performed according to ASTM F382. -Breaking torque testing was performed according to ISO 6475. -Engineering analysis was performed to compare the structural properties per ASTM F382 A1 (bending stiffness, bending structural stiffness, and bending strength) of the proximal tibia plate (subject device) and proximal tibia plate (predicate device one). -Engineering analysis and comparison of technology was also provided to compare design and dimensions of the subject and predicate plates and screws.
Clinical Testing:	Clinical testing is not a prerequisite, as osteosynthesis, osteotomy, and arthrodesis implants conform to recognized standards and have well established safety and performance characteristics. Therefore, clinical information is not necessary to demonstrate safety and effectiveness or substantial equivalence.
Conclusion:	The Traufix osteosynthesis, osteotomy, and arthrodesis devices have been found to be substantially equivalent to the predicate devices. Differences between the subject devices and the predicate devices do not raise new questions of safety or effectiveness.