DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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December 28, 2016

Gexfix International Corp.
% Roger Gray
VP, Quality and Regulatory
Donawa Lifescience Consulting S.R.L.
Piazza Albania, 10
Rome, 00153 Italy

Re: K160972
Trade/Device Name: Gexfix External Fixation
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: KTT
Dated: November 23, 2016
Received: November 28, 2016

Dear Roger Gray:

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. 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); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Caroline Rhim -S

for

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K160972

Device Name

Gexfix External Fixation

Indications for Use *(Describe)*

1) Bone fracture fixation
2) Osteotomy
3) Arthrodesis
4) Correction of deformity
5) Revision procedures where other devices have been unsuccessful
6) Bone reconstruction procedures

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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APPENDIX E

510(k) Summary in accordance with 21 CFR 807.92(c)

Type of Submission:	Traditional 510(k)
Date of Submission:	21 November 2016
Device Proprietary Name:	Gexfix External Fixation
FDA Product Code:	KTT
FDA Regulation Number:	21 CFR 888.3030
FDA Classification Name:	Single/multiple component metallic bone fixation appliances and accessories
FDA Identification:	Single/multiple component metallic bone fixation appliances and accessories are devices intended to be implanted consisting of one or more metallic components and their metallic fasteners. The devices contain a plate, a nail/plate combination, or a blade/plate combination that are made of alloys, such as cobalt-chromium-molybdenum, stainless steel, and titanium, that are intended to be held in position with fasteners, such as screws and nails, or bolts, nuts, and washers. These devices are used for fixation of fractures of the proximal or distal end of long bones, such as intracapsular, intertrochanteric, intercervical, supracondylar, or condylar fractures of the femur; for fusion of a joint; or for surgical procedures that involve cutting a bone. The devices may be implanted or attached through the skin so that a pulling force (traction) may be applied to the skeletal system.
FDA Panel:	Orthopedic
FDA Classification:	Class II
510(k) Owner/Submitter:	Gexfix International Corporation (previously registered as Gexfix USA Inc.) 55 NE Avenue, Suite 501 Boca Raton, FL 33432 USA
FDA Registration Number:	3005112659
Device Manufacturer:	Gexfix S.A. Avenue de la Praille 50 CH-1227 Carouge Switzerland Tel: +41 22 308 16 70 Fax: +41 22 308 16 79

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FDA Registration Number: 3005157180

510(k) Correspondent:

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Intended Use / Indications for Use:

1) Bone fracture fixation
2) Osteotomy
3) Arthrodesis
4) Correction of deformity
5) Revision procedures where other devices have been unsuccessful
6) Bone reconstruction procedures

This statement of intended use/indications for use is identical to that for the predicate device, as cleared under K052605.

Device Description:

The use of External Fixation devices provides surgeons with a means of bone fixation for the management of fractures and reconstructive surgery.

The Gexfix devices, in common with similar devices from other manufacturers, are intended only to assist during the healing process, and so are not intended to replace normal bone structures.

The Gexfix External Fixation devices are intended use a physical mechanism of action to hold bones in positions that aid stability during healing, thus facilitating the normal healing process. Some elements of the system are implantable during the healing process, with the main structural support being provided by external mechanical elements.

The Gexfix range includes external fixation devices for use in a variety of orthopedic applications. They are supplied non-sterile for single use, although some accessory items can be reused. Users are instructed to sterilize the components before use, using a sterilization cycle validated to achieve a sterilization Assurance Level (SAL) of at least 10^{-6}.

The Gexfix range of external fixation devices comprises three main elements, these being:

- Invasive components
- External components
- Ancillary components

This submission covers new components of the Gexfix system that are being added to the range of all three of the above types of component when compared with the predicate device. Some new components have an extended range of available dimensions, while other new components are

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additions to the range, to fulfil user needs for greater variety in the range of surgical applications, such as the introductions of components to allow external fixation of bones in the fingers, feet and shoulder.

Biocompatibility of patient-contacting materials is assured by using materials that meet applicable standards (e.g. for stainless steel and titanium alloy components) or by using materials which have received previous 510(k) clearance (e.g. PEEK).

Nonclinical testing:
Testing of the new components has been conducted on the basis of compliance with ASTM F1541-02(2011), 'Standard Specification and Test Methods for External Skeletal Fixation Devices'.

Testing has included, as appropriate to the constructs concerned, mechanical testing in:

- Bending
- Traction
- Compression
- Sliding
- Torsion
- Pin push-out

Tests were carried out on the following components/constructs:

- Digifix and mini-pins
- K-wires
- Lateral entry connections
- Shoulder osteosynthesis device (DOS)
- External fixation
- Minibone
- Gex-foot
- Caslau bar
- Pins
- Implantable elements

All tests resulted in the components being tested meeting predetermined acceptance criteria.

Labeling
MR Environment labeling has been introduced in accordance with ASTM F2503–13, 'Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment'.

Unique Device Identification labeling has also been introduced.

Substantial equivalence:
The predicate device for comparison with Gexfix External Fixation is the original version of the device, as cleared by FDA in K052605:

Predicate Device:.....Gexfix External Fixation
Sponsor:.....Gexfix USA, Inc. (now Gexfix International Corporation)
510(k) Number: K052605
Clearance Date: .....10 November 2005
FDA Product Code: .....KTT
Classification Name: .....Single/multiple component metallic bone fixation appliances and accessories

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Regulation No:.....21 CFR 888.3030

The subject device and the predicate devices have many identical or similar properties or features and share identical intended uses and indications for use.

The fundamental technology of the original and modified device is unchanged. Both the original and extended range of components in the Gexfix External Fixation comprise various elements that can be assembled by the orthopedic surgeon to help treat a wide variety of bone fractures and associated conditions. The range includes elements which are invasive, including those for temporary implantation; elements which are attached to the invasive components but which themselves are external to the patient; and elements that are required in order to either assemble the invasive and external components together, or to aid in the temporary implantation process.

The technical specifications are identical between the two devices except for the following:

Invasive components:

- The introduction of titanium (Ti6Al4V) versions of components alongside the original stainless steel versions
- An extension of the range of available dimensions of certain components

External components:

- The introduction of Lateral Entry Connection components
- The introduction of the Shoulder Osteosynthesis Device (DOS)
- The introduction of Digifix
- The introduction of Adynex
- The introduction of Gex-finger
- The introduction of Caslau Bar
- The introduction of Gex-foot
- The introduction of Minibone
- The introduction of titanium (Ti6Al4V) versions of certain components
- An extension of the range of available dimensions of certain components

Ancillary components:

- The introduction of two new components: Allen Key, Universal Key, K-wire Finger Implantation Guide
- An extension of the range of Trays available

The original device and the subject device interact with the patient in exactly the same ways.

The original device and the subject device interact with other devices in exactly the same way.

These differences have no significant effect on the safety or effectiveness of the subject device.

Summary:
All of the new range additions detailed in this submission have been reviewed and tested, and none have been identified as having any significant effect on the safety and effectiveness of the device when compared with the predicate.

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Substantial Equivalence Conclusion:
Based on the information contained within this submission, it is concluded that the components that make up the extension to the range of components in the Gexfix External Fixation device are substantially equivalent to the identified predicate device components cleared under K052605, which are already in interstate commerce within the USA.