SUMMARY OF SAFETY AND EFFECTIVENESS

MAR 1 4 2011

March 11, 2010

Trade Name: Newfix® External Fixation System

Common Name: External Fixation System

Applicant:

Tecnología y Diseño Industrial, S.A.P.I. de C.V.
José Adán Ortega Torres
Operation Manager

José Guadalupe Zuno 48 Col. Parque Industrial los Belenes
Zapopan, Jalisco
Mexico, C.P. 45101

Tel: +52 (33) 38 36 45 00 Ext. 2960 +52 (33) 36245132
Fax: +52 (33) 38 36 45 02

Classification Name: Single/multiple component metallic bone fixation appliances and accessories

Classification Panel: Orthopedic

All questions and/or comments concerning this document should be made to:

Robert J. Bard, Esq.
Managing Director

HealthCare Technologies Consultants
PO Box 506
South Lyon, MI 48178
Tel: 248-573-5040
Cell: 734-330-5990
email: rbard@reglaw.net

K101138

1.0 DEVICE SUMMARY

The Tecnología y Diseño Industrial, S.A. de C.V. Newfix® External Fixation System consists of various components including fixators, clamps, bars, distractors, carbon fiber rod, and stainless steel rods for use in orthopedic and trauma treatments.

1.1 Classification Information

Table SE1: Device Classification

Classification or descriptor	Name or designation
Common Name	External Fixation System
Device Trade Name	Newfix® External Fixation System
Device Classification Name	Single/multiple component metallic bone fixation appliances and accessories
Device Classification	Class II
Reviewing Panel	Orthopedic
Regulation Number	21 CFR 880.3030
Product Code	KTT

2.0 PREDICATE DEVICES

The Newfix® External Fixation System is substantially equivalent to the following predicate products.

Table SE2: Predicate Products

Manufacturer and Product	Cleared Predicate Product
Orthofix Modulsystem Dynamic Axial Fixation System	K831576, k955848
Synthes ® External Fixation System	K961350, k011034, k090658
Extrafix External fixation System by QFX Technologies	k091258
Smith & Nephew External Fixation System	K994143
Hoffmann II Compact External Fixation System	K971755
Zimmer Wristore Distal Radius Fracture Fixator	k012294
Tecnología y Diseño Industrial (TDI) Newfix Screw, Wire, and Fixation System	K101254
Treu-Instrumente GmbH Bone Fixation Screws and Pins	K083912

k101338

3.0 INTENDED USE AND INDICATIONS FOR USE

The Newfix® External Fixation System, consisting of axial fixators and frame components, is indicated for stabilization of open and/or unstable fractures where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. NEWFIX® External Fixation System is intended for the fixation and for temporary or extended stabilization in cases such as: open fractures, closed fractures, poly-trauma fractures, supplement in the stabilization of minimal fixations in intra and extra articular fractures.

4.0 DEVICE DESCRIPTIONS

4.1 The Newfix External Fixation System is a modular system that consists of various components including clamps, distractors, pins, carbon fiber rod, and stainless steel tubes for use in orthopedic and trauma treatment.

4.2 The system is a modular design to provide options in frame construction, simplicity in frame components, and ease of use. The system is comprised of aluminum and stainless steel clamps (rod-to-rod and pin-to-rod), stainless steel fixation pins and stainless steel and carbon fiber connector rods. Pins include smooth and self drilling/self-tapping type threaded pin with diamond tip and cutting edges.

4.3 The Newfix® External Fixation System is supplied non sterile and is intended for single patient use. None of the components of the Newfix System are reusable. The Newfix® External Fixation System includes instruments and accessory devices necessary for its use.

5.0 COMPARISON OF DEVICE UNDER REVIEW AND ITS PREDICATES

Comparison Element	**TDI Newfix ® External Fixation System K101338**	**Orthofix Modulsystem Dynamic Axial Fixation System K955848**	**Synthes®. External Fixation System** K961350, k011034, k090658	**XtraFix (Extrafix) External fixation System k091258**
Manufacturer	Tecnología y Diseño Industrial S.A.P.I. de C.V.	Orthofix	Synthes (USA)	ExtraOrtho (QFX Technologies)
Indication for/ Intended Use	The Newfix® External Fixation System, consisting of axial fixators and frame components, is indicated for stabilization of open and/or unstable fractures where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. NEWFIX® External Fixation System is intended for the fixation and for temporary or extended stabilization in cases such as: open fractures, closed fractures, poly-trauma fractures, supplement in the stabilization of minimal fixations in intra and extra articular fractures.	Orthofix Dynamic Axial Fixation System is a unilateral external fixation device, which is intended for use in the treatment of bone conditions including leg lengthening, osteotomies, arthrodesis, fracture fixation and other bone conditions amenable to treatment by use of the external fixation modality."	The Synthes (USA) External Fixation Systems (K961350, k011034, k090658) are intended for use in the construction of an external fixator frame for the treatment of pediatric and adult fractures.	The Extrafix External Fixation System (k091258) includes various elements designed to build a fixator construct. The system includes clamps, posts, bars, and fixation pins. The Extrafix External Fixation System is indicated for use in construction of an external fixation frame for treatment of long bone (foot, femur, and tibia) and pelvic fractures that require external fixation. Specifically, the system is intended for: o Temporary stabilization of open or closed acute fractures with soft tissue injuries; o Definitive stabilization of open or closed fractures where open or alternative closed treatment is undesirable or otherwise contraindicated; o Stabilization of fractures in the context of polytrauma; o Temporary or definitive stabilization of certain pelvic fractures or pelvic ring injuries; o Arthrodesis and osteotomies with associated soft tissue problems; o Stabilization of limbs after removal of total joint (knee and ankle) arthroplasty for infection or other failure; o Neutralization of fractures stabilized with limited internal fixation; o Stabilization of non-unions; and o Intraoperative temporary stabilization tool to assist with indirect reduction.

K101338

Comparison Element	**TDI Newfix ® External Fixation System K101338**	**Orthofix Modulsystem Dynamic Axial Fixation System K955848**	**Synthes®. External Fixation System** K961350, k011034, k090658	**XtraFix (Extrafix) External fixation System k091258**
Materials	Carbon fiber Stainless Steel 17-4PH (AISI 630) Stainless steel 304 Titanium alloys Aluminum 6061-T6 Stainless steel 316LS	Aluminum, stainless steel, titanium, and composite materials	Clamps -Stainless steel and titanium alloy Dynamization Clip - Stainless steel Rod Attachment - Stainless steel and titanium alloy Rods - Carbon fiber reinforced epoxy (CFRE) Screws – stainless, titanium alloys	Aluminum, stainless steel, titanium, and composite materials
Duration of Use	Greater than 30 days	Greater than 30 days	Greater than 30 days	Greater than 30 days
Reuse Capability	Single use	Single use	Single use	Single use

K101338

k101338

5.1 Performance Tests

5.1.1 Performance tests were conducted to validate the locking mechanism of the Newfix External Fixation System against various components of the Orthofix predicate devices.

TDI Products tested:

- E0300104 Lateral Cylinder for Pins (Straight Clamp).
- E0600201 T-Shaped Clamp.
- E0600301, Angled Clamp.
- E0600401 Ankle Clamp.
- E0900104/5 RadioLucent Wrist Axial Fixator Clamp.

Predicate Devices tested:

- Orthofix ProCallus Fixator Straight Clamp
- Orthofix T-Shaped Clamp
- Orthofix Ankle Clamp
- Orthofix RadioLucent Wrist Fixator Clamp

Materials used:

- Ø6mm (0.236in) and Ø4mm (0.157in) series 316 stainless steel rods.
- Ø6mm (0.236in) and Ø4mm (0.157in) series 316 stainless steel rods with a hexagonal nut for torque tests.
- Socket Set Screws Flat Point ISO 4026 M8x1.25.

Measuring tools:

- TDI.QC.023 PTS Analog push pull gauge SKN-5 S/N3409090760
- TDI.QC.027 Dial torque wrench 6178A S/N 0207801708

Referenced Standards

- ASTM F 1541 Standard Specification and Test Methods for External Skeletal Fixation Devices.
- ASTM E 4 Practices for Force Verification of Testing Machines

6.0 CONCLUSION

6.1 Interconnection testing per ASTM F 1541 and engineering analysis comparing lock mechanisms demonstrated equivalence to predicates.

6.2 The Newfix External Fixation System is substantially equivalent to the identified predicate systems based on the substantial equivalence of indication for use, design features, operating principles, performance tests and material of composition.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Technologia y Diseño Industrial, S.A.P.I. de C.V.
% Healthcare Technologies Consultants
Mr. Robert Bard
PO Box 506
South Lyon, Michigan 48178

MAR 14 2011

Re: K101338
Trade/Device Name: Newfix® External Fixation System
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: February 25, 2011
Received: March 01, 2011

Dear Mr. Bard:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indication for Use

510(k): k101338

Device Name: Newfix® External Fixation System

The Newfix® External Fixation System, consisting of axial fixators and frame components, is indicated for stabilization of open and/or unstable fractures where soft tissue injury precludes the use of other fracture treatments such as IM rodding or casting. NEWFIX® External Fixation System is intended for the fixation and for temporary or extended stabilization in cases such as: open fractures, closed fractures, poly-trauma fractures, supplement in the stabilization of minimal fixations in intra and extra articular fractures.

Prescription Use __X___ and/or Over the Counter Use ____
(21 CFR Part 801 Subpart D) (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for M. Melkerson

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k)_____

510(k) Number K101338