K101254 (1/3)



# SUMMARY OF SAFETY AND EFFECTIVENESS

July 13, 2010

**Trade Name:** Newfix Screw, Wire and Pin Fixation System

**Common Name:** Screw, Fixation, Bone

JUL 15 2010

Applicant:

Tecnología y Diseño Industrial, S.A. de C.V.
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**Classification Name:** Smooth or threaded metallic bone fixation fastener

**Classification Panel:** Orthopedic

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

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K101254 (2/3)



## 1.0 DEVICE SUMMARY

The Tecnología y Diseño Industrial, S.A. de C.V. Newfix® Screw, Wire and Pin Fixation System of devices are a family of external fixation pins and screws for use in orthopedic treatment fractures.

1.1 Classification Information

Table SE1: Device Classification

| Classification or descriptor | Name or designation |
|---|---|
| Common Name | Smooth or threaded pin |
| Device Trade Name | Newfix Screw, Wire and Pin Fixation System |
| Device Classification Name | Smooth or threaded metallic bone fixation fastener |
| Device Classification | Class II |
| Reviewing Panel | Orthopedic |
| Regulation Number | 21 CFR 880.3040 |
| Product Code | HWC |

## 2.0 PREDICATE DEVICES

The Newfix Screw systems are substantially equivalent to the following predicate products.

2.1 Treu-Instrumente GmbH Bone Fixation Screws and Pins

2.1.1 510(k) Number: k083912

## 3.0 INTENDED USE AND INDICATIONS FOR USE

The Newfix® Screw, Wire and Pin Fixation System is intended to be used as implants for the fixation of bone fractures, fusion of joints or bone reconstructions or as guide pins for insertion of other implants.

## 4.0 DEVICE DESCRIPTIONS

4.1 The Newfix® Screw, Wire and Pin Fixation System is a family of threaded external fixator of various sizes for use in the treatment of fractures.

4.2 Pins include smooth and self drilling/self-tapping type threaded pin with diamond tip and cutting edges.

4.3 The pin and screws of the Newfix System are manufactured using implant grade stainless steel.

4.4 Pin configurations include Kirschner Pins (K-wires), Schanz Screws, Steinmann Pin and Conic Threaded Bone Screws all in various lengths, diameters and threads.

4.4.1 Dimensional specifications

Table SE2: Dimensional specs

| Pin Type | Diameter (Ø) | Length |
|---|---|---|
| Kirschner pin (K-wire) | Ø 1.6 – 2.5 mm | 100 – 400 mm |
| Schanz screw | Ø 2.5 – 6 mm | 60 – 250 mm |

| | | |
|---|---|---|
| Steinmann pin | Ø 3.5 – 5 mm | 150 – 250 mm |
| Conic pin | Ø 4-3.0/2.5 – 6/5 mm | 60 – 220 mm |

4.5 The Newfix® Screw, Wire and Pin Fixation System is intended for single patient use. None of the components of the Newfix System are reusable.

4.6 The Newfix® Screw, Wire and Pin Fixation System includes the following accessory devices: Depth Gauge; Tissue Protection Triple Guide for Axial Fixation; T Shape Handle Chuck; and Drill Bits.

## 5.0 COMPARISON OF DEVICE UNDER REVIEW AND ITS PREDICATES

5.1 Comparison of Devices

| Comparison Element | TDI Newfix® Screw, Wire and Pin Fixation System | TREU-INSTRUMENTE GmbH Bone Fixation Screws and Pins |
|---|---|---|
| Manufacturer | Tecnología y Diseño Industrial, S.A. de C.V. | TREU-INSTRUMENTE GmbH |
| Indication for/ Intended Use | The Newfix® Screw, Wire and Pin Fixation System is intended to be used as implants for the fixation of bone fractures, fusion of joints or bone reconstructions or as guide pins for insertion of other implants. | The Treu Bone Fixation Screws and Pins are intended to be used as implants for the fixation of bone fractures, fusion of joints or bone reconstructions or as guide pins for insertion of other implants. |
| Materials | Stainless Steel 316 LS/LVM Implant Grade. | Titanium and stainless steel (ISO 58/32-1) |
| Duration of Use | Greater than 30 days | Greater than 30 days |
| Reuse Capability | Single use | Single use |
| Fixation | Pins/Screws | Pins/Screws |
| Sterility | Non-sterile (to be sterilized prior to use) | Non-sterile (to be sterilized prior to use) |

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

Technología y Diseño Industrial SA DE CV
% Mr. Robert J. Bard, JD
P.O. Box 506
South Lyon, Michigan 48178

JUL 15 2010

Re: K101254
Trade/Device Name: Newfix Screw, Wire and Pin Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: II
Product Code: HWC
Dated: April 29, 2010
Received: May 4, 2010

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.

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,

for 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

JUL 15 2010

510(k): K101254

Device Name: Newfix Screw, Wire and Pin Fixation System

Indication for Use: The Newfix Screw, Wire and Pin Fixation System is to be used as implants for the fixation of bone fractures, fusion of joints or bone reconstructions or as guide pins for insertion of other implants.

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)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

for mxm

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

510(k) Number K101254