JUN - 5 1997

K971272

510(k) Premarket Notification Summary of Safety and Effectiveness Information	Trauma-Fix® External Fixator

Regulatory Authority: Safe Medical Devices Act of 1990, 21 CFR 807.92

1. **Device Name:**

   Trade Name: **Trauma-Fix® External Fixator**

   Common Name: External Fixator

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

3. **Establishment Name & Registration Number:**

   Name: Trend Medical, Inc.

   Number: Pending

4. **Classification:**

   accessories. (a) 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. (b) Classification. Class II.

   Product Code: Unknown

   Device Class: Class II

   Classification Panel: Orthopaedic and Rehabilitation Devices

5. **Contact Person:**

   Mr. Gordon Tao
   Trend Medical, Inc.
   14433 Catalina Street
   San Leandro, CA 94577

6. **Special Controls:**

   Special controls have not been established for this device.

7. **Description of the Device:**

Background: The **Trauma-Fix® External Fixator** is offered as both a unilateral (uni-bar) and quadrilateral style (also called multi-plane) external fixation frame. External fixators known as uni-bar and multi-plane are typical of present industry standard designs. The uni-bar fixator concept is an outgrowth of the multi-plane fixator varying chiefly in the use of half-pins rather than the transfixing pins typical of multi-plane fixation, though occasionally half-pins are used with multi-plane fixators.

Unilateral frames using half pins and multi-plane fixators using half pins and transfixing pins were developed and popularized by Dr. Hoffmann near the turn of the century with the devices' seeing much use in Germany during the First World War. At the time the external fixation concept was not much appreciated in this country. Doctor Hoffmann used his device in the management of gun shot wounds involving significant tissue and bone loss of the extremities. In the era prior to antibiotic therapy, such injuries frequently led to sepsis, amputation or death if primary wound closure or casting alone were attempted. Limb salvage under these conditions required the ability to immobilize the bony and soft injury and to irrigate or debride the soft tissue injury daily for an extended period of time. Casting and wound closure could be eliminated or delayed as needed to manage infection, granulation healing and fracture healing. An added benefit was the fact that some weight bearing was possible and limb shortening could be reduced or eliminated.

Uni-bar fixation using half-pins for the treatment of various long bone fractures and trauma was an outgrowth of the multi-plane transfixing pin concept. The chief benefit of uni-bar fixation is that it is generally a less complex method of fracture fixation and open wound management than is treatment with the multi-plane fixator. As a result, the uni-bar technique is usually easier. The limitation of the uni-bar technique is that it provides less adjustment or tolerance for significant rotational deformities or weight bearing. Also, when large axial compressive or distractive forces are encountered there can be a tendency for the axis of the long bone to deflect due to the lack of bilateral or multi-plane support provided by the additional connection rods of a multi-plane fixator construct.

The functional basis for the **Trauma-Fix® External Fixator** line is to provide fixators that allow the practitioner the option to use the appropriate fixator for the presenting fracture injury type. Open wound orthopaedic management without significant weight bearing or high fracture site compression requirements may be addressed in a simple cost effective manner.

The **Trauma-Fix® External Fixator** line is made up of the following items:

Fixator

Pin Holder Clamps, 5 & 8 mm diameter
Articulation Coupling, 5 & 8 mm diameter
Connecting Rods, 5 & 8 mm diameter
Adjustable Telescopic Connecting Rods, 5 & 8 mm diameter
Small Lengthining Device for Forearm
Colles Forearm Frame
Half-Pins
Full-Pins/Transfixing Pins
KTB Wires
Uni-Bar Pin Clamp
Uni-Bar Smooth Rods
Uni-Bar Compression & Distraction Rod
Uni-Bar Connector

Instruments

Drill Brace
Chuck, 3, 4, 5, 6, mm
T-Wrench
Open Wrench
Hex Screw Driver
Drill Bit
Trochar & Sleeve

In summary, uni-bar-type fixators offer simple design, ease of use and rapid stable fixation. Quadrilateral frames provide a more complex structure but also offer maximum flexibility and will allow for complex fracture reduction in all three planes, anterior, posterior and axial rotation. Both frame types are designed to be disposable and are not recommended for reuse.

8. **Comparison to Predicate Device(s):**

Four currently available external fixation devices have been selected for comparison.

1. **OrthoFrame™** by Thera-Kinetics, Inc. Comparison based on design and indications for use.

2. **Hoffman-Type External Fixation** by Zimmer, Inc. Comparison based on design, and indications for use.

3. **ACE-Fischer™ Fixator** by **DePuy**ACE. Comparison based on design, materials and indications for use.

4. **ACE-Align Fixator™** by **DePuy**ACE. Comparison based on design, materials and indications for use.

The **OrthoFrame™** is an example of a unilateral external fixator. This particular device is made from composite materials.

The Zimmer brand **Hoffman-Type External Fixation** is an example of an essentially unchanged Hoffmann-type external fixator. This device is essentially identical to Dr. Hoffmanns original devices. Made from certified stainless steel.

The **ACE-Fischer™ Fixator** is an example of a more modern design multi-plane fixator. The multi-plane fixator is analogous to the quadrilateral multi-plane fixator. The device is made from titanium alloy (6Al, 4V, ti) and aluminum.

The **ACE-Align Fixator™** is also an example of a unilateral external fixator. This particular device is made from titanium alloy (6Al, 4V, ti) and aluminum.

9. **Packaging:**

Plastic bags, peel pouches, and clear tubes are used to contain the individual device components and or pins. The packaging selected for use is sufficient to identify, protect and transport the devices safely. Shipper materials are standard, paper fiber industry typical bulk box-type shipper packaging.

10. Sterilization/Re-sterilization:

All fixation pins, instruments and external fixation compression and distraction components are supplied **Non-Sterile.** Non-Sterile implants are packaged in "clean only" condition but are free of manufacturing debris and residue. Each component is inspected after processing to evaluate and document the removal of manufacturing residue and debris. However, it is recommended that all pins, frames and clamps be removed from their shipping and packing materials and washed and rinsed thoroughly before storage and or sterilization.

The recommended sterilization method, time and temperature for the implants is gravity steam sterilization for 15 minutes at 134° C (270° F). The Sterility Assurance Level (SAL) of this recommended sterilization cycle is 10^{-6} (SAL 10^{-6}). Validation of the recommended cycle has been conducted by a qualified commercial laboratory. The validation method used is known as the overkill method. Other steam sterilization cycle time and temperature conditions may also render the device sterile.

The recommended sterilization method is based on Health Industry Manufacturers Association (HIMA) & the Association of Operating Room Nurses (AORN) protocols. Some health care facilities may wish to use other variations of the HIMA & AORN sterilization recommendations. However, individuals or hospitals not using the recommended method, temperature and time should validate any alternative sterility processing method using appropriate laboratory techniques.

12. Conclusion:

Based on the materials, intended uses, design, long standing safety and effectiveness use of the concept, the **Uni-bar™ External Fixator** unit is equivalent to the referenced legally marketed comparison external fixation devices. The feature comparison chart below graphically demonstrates this equivalence.

13. Comparison Table:

FEATURE	Trauma-Fix® External Fixator	Zimmer Hoffmann	OrthoFrame	Ace	SE?
Intended Use:	External fixation of long bone fractures. External fixation and stabilization of surgical osteotomy sites. Leg lengthening procedures. Knee, hip and ankle arthrodesis. External fixation of septic and aseptic non-union of long bones Pelvic fixation	Same	Same	Same	Yes
Distraction	Yes	Yes	Yes	Yes	Yes
Compression:	Yes	Yes	Yes	Yes	Yes
Materials:	Aluminum & Stainless	Stainless steel	Composite	Al, Ti & Stainless	Yes
Design:	Uni-lateral & Quadrilateral	Quadrilateral	Uni-lateral	Uni-lateral & Multi-plane	Yes
Half Pins:	Yes	Yes	Yes	Yes	Yes
Transfix Pins:	Yes	Yes	Yes	Yes	Yes
Instruments:	Yes	Yes	Yes	Yes	Yes
Per. Standards:	ASTM - ISO	ASTM - ISO	ASTM - ISO	ASTM - ISO	Yes
Disposable:	Yes	No	No	No	No
Sterilization:	Steam	Steam	Steam	Steam	Yes
Manufacturer:	Trend Medical	Zimmer	Thera-Kenitics	DePuy/ACE	Yes

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 5 1997

Mr. David W. Schlerf
Buckman Company, Inc.
Representing Trend Medical, Inc.
1000 Burnett Avenue, Suite 450
Concord, California 94520

Re: K971272
Trauma-Fix® External Fixator
Regulatory Class: II
Product Code: KTW
Dated: March 17, 1997
Received: April 4, 1997

Dear Mr. Schlerf:

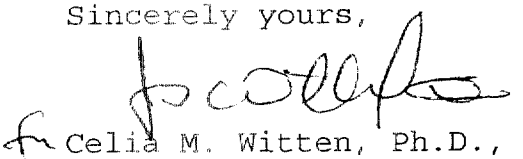
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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). 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 (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,



for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K971272

Device Name: Trauma-Fix® External Fixator

Indications For Use:

1. External fixation of long bone fractures.
2. External fixation and stabilization of surgical osteotomy sites.
3. Leg lengthening procedures.
4. Knee, hip and ankle arthrodesis.
5. External fixation of septic and aseptic non-union of long bones
6. Pelvic fixation

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NECESSARY

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restoretive Devices
510(k) Number K971272

Prescription Use X OR Over-The-Counter Use _____

(Per 21 CFR 801.109) (Optional format 1-2-96)