K994143

FEB 1 8 2000

510(K) Summary of Safety and Effectiveness
Smith & Nephew External Fixation System

Substantial Equivalence Information

In the table below, components in the *Smith & Nephew External Fixation System* listed in the left column are substantially equivalent to the legally marketed predicate devices shown in the column on the right. 510(k) numbers for the legally marketed, predicate devices are provided in **Table 18** (see **Exhibit 17**).

Smith & Nephew External Fixation System	Legally Marketed Predicate Device
Unilateral External Fixation System	Hex-Fix® Field Fixator – Smith & Nephew
Unilateral Wrist External Fixator with Double Ball Joints (DBJ)	Richards Colles Fracture Frame – Smith & Nephew
Unilateral Wrist External Fixator for Distal Radius Fractures (DFR)	Simple Small External Fixator – Synthes
Proximal Interphalangeal (PIP) Joint Hinge	Compass® Universal Hinge – Smith & Nephew
Multilateral External Fixation System	Richards External Fixation System – Smith & Nephew
Taylor Spatial Frame External Fixation System	Taylor Spatial Frame External Fixation System – Smith & Nephew
Ankle Hinge Fixator	Compass® Universal Hinge – Smith & Nephew

All of the devices listed above have similar indications for use, similar material composition and utilize similar designs. The safety and effectiveness of external fixators is based on the long history of use of these devices in the orthopedic market place.

Indications for Use

- Post-traumatic joint contracture which has resulted in loss of range of motion.
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction.
- Open and closed fracture fixation.
- Pseudoarthrosis of long bones.
- Limb lengthening by epiphyseal or metaphyseal distraction.
- Correction of bony or soft tissue deformities.
- Correction of segmental bony or soft tissue defects.
- Joint arthrodesis.
- Infected fractures or nonunions.
- Management of comminuted intra-articular fractures of the distal radius.

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Device Description

The Smith & Nephew Unilateral External Fixator is a *unilateral* external fixation device used for the indications listed previously. Major components are made of aluminum, stainless steel and composite materials with some fastener components made from bronze or rubber. These materials are similar to those used in other legally marketed *unilateral* fixators.

The Smith & Nephew Unilateral Wrist Fixators are *unilateral* external fixation devices used for the indications listed previously. All components are made from stainless steel, aluminum or composite materials. These materials are similar to those used in other legally marketed *unilateral* wrist fixators.

The Smith & Nephew Proximal Interphalangeal (PIP) Joint Hinge is a *unilateral* fixation device used for the indications listed previously. Major components are made from a radiolucent, non-reinforced thermoplastic. Various other components and fasteners are made from stainless steel. These materials are similar to those used in other legally marketed *unilateral* fixators.

The Smith & Nephew Multilateral External Fixation System is a *multilateral* fixation device used for the indications listed previously. Major components are made from stainless steel, aluminum or composite materials. These materials are similar to those used in other legally marketed *multilateral* fixators.

The Taylor Spatial Frame External Fixation System is a multilateral fixation device used for the indications listed previously. Major components are made from stainless steel, aluminum or composite materials. These materials are similar to those used in other legally marketed *multilateral* fixators.

The Smith & Nephew Ankle Hinge Fixator is used with either a *unilateral* or *multilateral* fixation device for the indications listed previously. Major components are made from composite and stainless steel materials. These materials are similar to those used in other legally marketed *unilateral* or *multilateral* fixators.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 1 8 2000

Mr. David Henley
Clinical/Regulatory Specialist
SMITH & NEPHEW, INC.
1450 Brooks Road
Memphis, Tennessee 38116

Re: K994143
Trade Name: External Fixation System
Regulatory Class: II
Product Code: JDW
Dated: December 7, 1999
Received: December 8, 1999

Dear Mr. Henley:

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 control provisions of the Act. The general control 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 current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) 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 at (301) 443-6597, or at its Internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

James E. Dillard III
Acting Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications Statement

Indications for use for the Smith & Nephew External Fixation System are as follows:

- Post-traumatic joint contracture which has resulted in loss of range of motion.
- Fractures and disease which generally may result in joint contractures or loss of range of motion and fractures requiring distraction.
- Open and closed fracture fixation.
- Pseudoarthrosis of long bones.
- Limb lengthening by epiphyseal or metaphyseal distraction.
- Correction of bony or soft tissue deformities.
- Correction of segmental bony or soft tissue defects.
- Joint arthrodesis.
- Infected fractures or nonunions.
- Management of comminuted intra-articular fractures of the distal radius.

MAD for JZD
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K994143

Prescription Use Yes
(Per 21 CFR 801.109)