K043289

FEB 11 2005

510K SUMMARY OF SAFETY AND EFFECTIVENESS

The E-Z Frame Surgical Boot is manufactured of light weight stable materials to allow the surgeon to stabilize the foot at or below the ankle for post surgical conditions. Presently Iiizarov or Sheppard Rings are used for this purpose and require multiple avenues of surgical intervention in the tibia to stabilize the distal support ring. With the E-Z Frame system a boot is stabilized on the distal leg (tibia) and further stabilized to the distal ring about the foot with carbon fiber rods that are attached to the boot and ring respectfully. Light weight materials are employed using 6061 Aluminum, ABS plastic, carbon fiber rods, FR10/11 laminate and small ASTM F 17-4 Stainless Steel Fixtures. The foot is stabilized to the distal ring using Kirshner Wires (K-Wire) purchased from PROMEX of Indianapolis, IN under 510 K: K960023. The boot utilized to stabilize the device on the tibia is purchased and modified from Darco International of Virginia.

Indications for Use:

1. Triple arthrodesis
2. Isolated rearfoot arthrodesis
3. Midfoot arthrodesis
4. Comminuted trauma
5. Diabetic Charcot reconstruction
6. Most foot pathology not requiring fixation above the ankle

Contact Information:

If further information is required, please contact Dr. Louis A. Serafin, Jr. at Signal Medical Corporation, 400 Pyramid Drive, Marysville, MI 48040. Phone 810-364-7070.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 11 2005

Louis A Serafin, Jr., MD
Signal Medical Corporation
400 Pyramid Dive
Marysville, Florida

Re: K043289
Trade/Device Name: E Z Frame
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: II
Product Code: KTT
Dated: January 31, 2005
Received: February 1, 2005

Dear Dr. Serafin:

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.

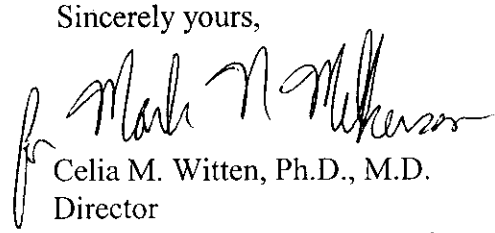
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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); 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.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



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

Enclosure

1

510(k) Number (If known):

Device Name: E Z Frame

Indications For Use:

Triple arthrodesis
Isolated rearfoot arthrodesis
Midfoot arthrodesis
Comminuted trauma
Diabetic Charcot reconstruction
Most foot pathology not requiring fixation above the ankle

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

for (Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) Number K043289

Prescription Use X **OR Over-The-Counter Use**
(Per 21 CFR 801.109)

(Optional Format