K122208

510(k) Summary

DEC 2 0 2012

Company Name:	Christopher D. Endara 11767 S. Dixie Highway, #313 Pinecrest, Florida 33156
Contact Name:	Christopher D. Endara 11767 S. Dixie Highway, #313 Pinecrest, Florida 33156 Phone (305) 491-9133
Date Prepared:	October 20, 2012
Trade Name:	External Fixation System
Common Name:	External Fixation
Classification:	21 CFR 888.3040: Smooth or Threaded Metallic Bone Fixation Fastener
Product Code:	NDK
Predicate Devices:	K101375, K973017, K971755, K030390, and K040258
Device Description:	The external fixation system includes various size components to accommodate various anatomies and injuries. The clamps enable the frame to be coupled to bone by securing the rods and Schanz Screws for the intended use. Components designed for this system are the medium clamp to accept the 8.0mm carbon fiber rod (100mm to 500mm length) and Schanz Screws (4.0mm diameter x 125mm length and 5.0mm diameter x 150mm to 200mm lengths), and the large clamp to accept the 11.0mm carbon fiber rod (100mm to 500mm length) and Schanz Screws (4.0mm diameter x 125mm length, 5.0mm diameter x 150mm length to 200mm lengths, and 6.0mm diameter x 225mm to 300mm lengths).
Intended Use:	The external fixation system is a device intended to be used in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

Substantial Equivalence:	The external fixation system has the same intended use, materials, and same technological characteristics as the predicate devices. Based on the information submitted, it is determined that the external fixation system is substantially equivalent to the currently marketed predicate devices.
Technological Characteristics Comparison:	The external fixation system is substantially equivalent to the predicate devices with respect to the design, function, and material.
Sterilization Information:	The external fixator system will be distributed non-sterile. The devices are sterilized by the end user per the AAMI Guidelines "Good Hospital Practice: Steam Sterilization and Sterility Assurance" and ANSI/AAMI/ISO 11737 guidelines to achieve the Sterility Assurance Level (SAL) of 10^{-6}.
Conclusion:	There are no significant differences between the external fixation system and the other devices as listed in the Substantially Equivalent Devices. The external fixation system and the predicate devices have similar design attributes, material, and intended use thus is considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

Letter dated: December 20, 2012

Christopher D. Endara
President
11767 South Dixie Highway, #313
Pinecrest, Florida 33156

Re: K122208
Trade/Device Name: External Fixation System
Regulation Number: 21 CFR 888.3040
Regulation Name: Smooth or threaded metallic bone fixation fastener
Regulatory Class: Class II
Product Code: NDK
Dated: November 15, 2012
Received: November 28, 2012

Dear Mr. Endara:

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

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

Enclosure

Indications for Use

510(k) Number: K122208

Device Name: External Fixation System

Indications for Use: The external fixation system is a device intended to be used in the treatment of bone conditions including limb lengthening, osteotomies, arthrodesis, fracture fixation, and other bone conditions amenable to treatment by use of the external fixation modality.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (Part 21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Krishna Asundi
Division of Orthopedic Devices