



Food and Drug Administration  
10903 New Hampshire Avenue  
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DNE, LLC  
% Christine Scifert  
Official Correspondent  
Memphis Regulatory Consulting, LLC  
3416 Roxee Run Cove  
Bartlett, Tennessee 38133

February 16, 2016

Re: K151580  
Trade/Device Name: D.N.E. External Fixation System  
Regulation Number: 21 CFR 888.3030  
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories  
Regulatory Class: Class II  
Product Code: KTT  
Dated: January 20, 2016  
Received: January 21, 2016

Dear Ms. Scifert:

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 Parts 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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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 -S**

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 (if known)

K151580

Device Name

D.N.E. External Fixation System

Indications for Use (Describe)

The D.N.E. Ring Fixator and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or metaphyseal distraction, correction or bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The D.N.E. Ring Fixator is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

**PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.**

**FOR FDA USE ONLY**

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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This section applies only to requirements of the Paperwork Reduction Act of 1995.

**\*DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.\***

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**Special 510(k) Summary**  
D.N.E. External Fixation System  
February 3, 2016

**Company:** D.N.E., LLC  
2225 Park Place Drive  
Slatington, Pa. 18080

**Primary Contact:** Christine Scifert  
3416 Roxee Run Cove  
Bartlett, TN 38133  
[scifert@memphisregulatory.com](mailto:scifert@memphisregulatory.com)

**Trade Name:** D.N.E. External Fixation System

**Common Name:** External Fixation Frame

**Classification:** Class II

**Regulation Number:** 21 CFR 888.3030

**Panel:** Orthopedic

**Product Code:** KTT

**Primary Predicate:** K113106 – D.N.E. External Fixation System

**Device Description:**

The D.N.E. External Fixation System assembly consists of three basic types of elements: 1) bone anchorage elements, 2) bridge elements, and 3) connection elements. The design allows freedom of pin placement, ease of assembly and stable fixation of bone fragments with the possibility of axial loading of the extremity and immediate range of motion of all adjacent joints.

An Angular Correction Clamp and associated Struts have been added to the system in order to facilitate a surgeons ability to step down in ring sizes.

**Indications for Use:**

The D.N.E. External Fixation System and its components are indicated for open and closed fracture fixation, pseudoarthrosis or nonunions of long bones, limb lengthening by epiphyseal or

metaphyseal distraction, correction of bony or soft tissue deformities, and correction of segmental or nonsegmental bony or soft tissue defects. The D.N.E. External Fixation System is for use on all long bones including: tibia, fibula, femur, humerus, radius and ulna.

**Substantial Equivalence:**

The D.N.E. External Fixation Angular Correction Clamp and associated Struts are substantially equivalent to the predicate plates, nuts, washers and rods previously cleared in K113106 in terms of intended use, mechanical safety and performances. The clamp and thicker struts add stability and strength to the system when compared with the existing components. Static and Dynamic Axial Compression testing was performed per ASTM F1541 and showed the subject device to be substantially equivalent to the predicate device.